

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. 8,241,284

PETITION FOR *INTER PARTES* REVIEW

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List of Exhibits

- Ex. 1001 U.S. Patent No. 8,241,284 (“284 Patent”)
- Ex. 1002 Prosecution History of U.S. Patent No. 7,473,253
- Ex. 1003 Prosecution History of U.S. Patent No. 8,241,284
- Ex. 1004 Declaration of Mr. David C. Yates
- Ex. 1005 *Curriculum Vitae* of Mr. David C. Yates
- Ex. 1006 U.S. Patent No. 5,674,220 to Fox et al. (“*Fox*”)
- Ex. 1007 U.S. Patent No. 5,891,142 to Eggers et al. (“*Eggers ‘142*”)
- Ex. 1008 U.S. Patent No. 5,800,449 to Wales (“*Wales*”)
- Ex. 1009 U.S. Patent No. 5,330,471 to Eggers et al. (“*Eggers ‘471*”)
- Ex. 1010 PCT App. No. PCT/US01/11340, PCT Publication No. WO02/080795, to Dycus et al. (“*Dycus PCT*”)
- Ex. 1011 U.S. Patent No. 5,396,900 to Slater et al. (“*Slater*”)
- Ex. 1012 U.S. Patent No. 5,599,350 to Schulze et al. (“*Schulze*”)
- Ex. 1013 U.S. Patent No. 5,403,312 to Yates et al. (“*Yates*”)
- Ex. 1014 U.S. Patent No. 5,540,684 to Hassler, Jr. (“*Hassler*”)
- Ex. 1015 U.S. Patent No. 5,443,463 to Stern et al. (“*Stern*”)

I. INTRODUCTION

Ethicon Endo-Surgery, Inc. (“Petitioner”) petitions for *inter partes* review (“IPR”) of claims 1 to 18 of U.S. Patent No. 8,241,284 (“‘284 Patent”) (Ex. 1001).

II. THE ‘284 PATENT

Patent Owner Covidien AG (“PO”) obtained the ‘284 Patent by arguing that adding insulative “stop members” to grasping surfaces of known electrosurgical instruments was a meaningful distinction over the prior art. As described in detail below, art not before the Examiner illustrates the fallacy of that argument, and shows that the benefits of stop members and their use on endoscopic devices were well known long before the earliest possible filing date of the ‘284 Patent. Thus, the claims of the ‘284 Patent are invalid and should be cancelled.

A. Overview of the ‘284 Patent

The ‘284 Patent is directed to a bipolar forceps for endoscopic surgical procedures. (Ex. 1001 at 1:17-19). These instruments are not new; in addition to its eight pages of “References Cited,” the ‘284 Patent provides a detailed overview of existing devices that “utilize both mechanical clamping action and electrical energy to effect hemostasis by heating the tissue and blood vessels to coagulate, cauterize, and/or seal tissue.” (*Id.* at 1:31-2:59, 3:4-28; Ex. 1004 at ¶ 26).

For example, the ‘284 Patent admits that “[s]everal journal articles have disclosed methods for sealing small blood vessels using electrosurgery.” (Ex. 1001 at 1:53-54). In known sealing devices, electrodes in a pair of jaws (sometimes

referred to as an “end effector”) are “charged to a different electric potential[s] such that when the jaw members grasp tissue, electrical energy can be selectively transferred through the tissue.” (*Id.* at 2:2-5). The ‘284 Patent 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 2:22-25).

Accordingly, the ‘284 Patent does not disclose the first endoscopic bipolar vessel sealing instrument capable of sealing both smaller and larger vessels. Indeed, it admits that Petitioner’s own U.S. Patent No. 5,674,220 to Fox et al. (“*Fox*”, Ex. 1006) “discloses a transparent **vessel sealing instrument** which includes a longitudinally reciprocating knife which severs the tissue once seated [sic - sealed].” (Ex. 1001 at 3:7-10).¹ The alleged invention instead involves non-conductive stop members associated with the jaw members “to control the gap distance between opposing jaw members and enhance the manipulation and gripping of tissue during the sealing and dividing process.” (*Id.* at 1:21-26).

This alleged point of novelty, however, was not new. *Fox* discloses stop members: an “island of insulation...establish[es] an insulative gap between the conductive surfaces.” (*See* Ex. 1006 at 4:25-29). Likewise, U.S. Patent No. 5,891,142 to Eggers et al. (“*Eggers ‘142*”, Ex. 1007), discloses various

¹ All emphasis herein added unless otherwise indicated.

configurations of insulative spacers “to space the tissue grasping surfaces apart an optimum distance, T, when substantially in a closed orientation.” (Ex. 1007, 3:46-52, *see also* 3:59-60).

Nor can the ‘284 Patent find patentability in the particular arrangements of non-conductive stop members recited in some of its dependent claims. The ‘284 Patent does not identify any differing functionality, much less benefits, of the arrangements of stop members in Figs. 6A-6F. (Ex. 1001 at 12:30-46 (speculating that other configurations “may be equally effective”); Ex. 1004 at ¶¶ 20-23). Notwithstanding, *Eggers ‘142* disclosed the stop member configurations claimed in the ‘284 Patent almost four years before the invention of the ‘284 Patent. (*See, e.g.*, Ex. 1007 at Figs. 8-10, 15, 17-18).

B. Prosecution of the ‘284 Patent

The claims of the ‘284 Patent and its parent, U.S. Patent No. 7,473,253 (“‘253 Patent”), were allowed because of arguments selectively focused on individual references, not on prior art combinations. When the prior art is properly viewed as described herein, the claims of the ‘284 Patent are obvious.

During examination of the ‘253 Patent, the Examiner rejected the pending claims over U.S. Patent No. 5,800,449 to Wales (“*Wales*”) (Ex. 1008) in view of EP Pub. No. 0 986 990 to Eggers et al. (“*Eggers*”), a European counterpart of *Eggers ‘142*. (Ex. 1002 at pp. 520-26). The Examiner reasoned that “[i]t would

have been obvious to have provided the jaws of Wales with the stop members of Eggers...” (*Id.* at p. 524). Applicant responded by admitting that “Eggers et al. do include a spacer region,” but asserted that the claimed stop members had a different purpose than those in Eggers. (*Id.* at p. 566). Specifically, while the Eggers spacers are provided to “**securely grasp** tissue and **extrude** the tissue into the recesses between the spacer regions to assure uniform and consistent power density along the current paths between the conductive surfaces”, the claimed stop members “**control] the distance** between the jaw members when tissue is held therebetween.” (*Id.*) (emphasis in original).²

After several rejections, Applicant filed the amendment on April 10, 2008 that preceded allowance of the ‘253 Patent. (Ex. 1002 at pp. 705-22). Therein, Applicant amended the claims to require “jaw members being independently movable with respect to the elongated shaft” and to require that “the distance between clamped jaw members is substantially uniform along the length of the jaw members.” (*Id.* at pp. 706-714). Focusing on Eggers (and ignoring the Examiner’s incorporation of Eggers’ stop members into *Wales*), Applicant argued that Eggers did not have jaws independently movable with respect to an elongated shaft and that there was not substantially uniform distance between the jaws when tissue was

² PO nonetheless admitted “another purpose of the spacer regions of Eggers et al. is to separate the grasping surfaces a distance ‘T’ when closed...” (*Id.*)

held. (*Id.* at pp. 717-719). Applicant’s only comment on *Wales* was that it “does not teach a ‘stop member...which controls the distance between the jaw members.’” (*Id.* at p. 719).

The Applicant filed the application that issued as the ‘284 Patent with claims broader than the claims of the ‘253 Patent in two respects: (1) they did not require “the jaw members being **independently** movable with respect to the elongated shaft” and (2) they did not define the geometry of the device “when tissue is held therebetween.” (Ex. 1003 at pp. 29-33). The Examiner rejected the continuation claims over *Wales* and *Eggers*. (*Id.* at pp. 176-182). Applicant amended and argued that *Wales*’ end effector included a serrated portion that “is not flat and is not configured to support a plurality of stop members thereon so that the plurality of stop members are disposed along the same plane with respect to one another.” (*Id.* at p. 250). It also argued that *Eggers*’ stop members did not extend along the length of tines 112 and 222. (*Id.* at p. 254). On the basis of these arguments, the Examiner allowed the claims. (*Id.* at pp. 260-264).

C. The Petition Relies On Previously Unapplied Combinations

This Petition relies on the stop members of *Eggers* ‘142 (Ex. 1007), a U.S. counterpart to the *Eggers* publication discussed during examination. Despite the Examiner’s consideration of the EP counterpart of *Eggers* ‘142, *Fox* (Ex. 1006), which was not relied-on during examination, demonstrates that PO’s arguments

about *Wales* were technically flawed. Contradicting PO's characterization of the art during examination, *Fox* discloses endoscopic bipolar forceps with end effectors having planar seal surfaces divided by a knife channel (*see, e.g.*, Ex. 1006 at Fig. 5, 4:46-5:24) and the use of stop members on such devices (*id.* at 4:25-29). *Fox* therefore shows that PO's arguments about the inapplicability of Eggers' stop members to devices like in *Wales* are contradicted by *Fox's* express art teachings.

U.S. Patent No. 5,599,350 to Schulze et al. ("*Schulze*") (Ex. 1012) is not cited on the face of the '284 Patent. While the other art relied on in this Petition was cited, it was buried among hundreds of references and not relied on by the Examiner. Moreover, the Examiner did not have the benefit of the declaration of David C. Yates (Ex. 1004), an expert in the field of the prior art and the '284 Patent (Ex. 1004 at ¶¶ 1-16, 27-29; Ex. 1005). Thus, the arguments herein are new, and prosecution of the '284 Patent should not preclude institution of this IPR.

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

Petitioner certifies that (1) the '284 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting IPR of the '284 Patent on the grounds identified herein; and (3) Petitioner has not filed a complaint relating to the '284 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 IPR of 18

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., 4545 Creek Rd., Blue Ash, OH 45242, is a wholly owned subsidiary of Johnson & Johnson, 1 One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. Both entities are real parties-in-interest.

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

The ‘253 Patent is a parent of the at-issue ‘284 Patent. U.S. Patent App. No. 13/584,194, filed August 13, 2012, is a currently pending continuation of the ‘284 Patent. Petitioner is unaware of other related matters per 37 C.F.R § 42.8(b)(2).³

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

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Petitioner consents to electronic service by email.

³ Petitioner is concurrently requesting IPR of PO’s U.S. Patent No. 7,887,536.

While this patent also claims stop members added to known electrosurgical devices, it is does not have any familial relationship with the ‘284 Patent.

VI. 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 person 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 as of April 6, 2001 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. 1004 at ¶¶ 28-29, *see also* ¶¶ 17-27).

VII. CLAIM CONSTRUCTION

The claims of the ‘284 Patent should be given their “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b). For a construction to be correct under this standard, that construction must be “consistent with the specification” of the patent. *In re Cuozzo Speed Tech., LLC*, Case No. 14-1301, slip op. at 12, 14-15 (Fed. Cir. Feb. 2, 2015).

A. “Jaw Members Movable With Respect To The Elongated Shaft”

Claim 12 is directed to an endoscopic bipolar forceps including an elongated shaft and “jaw members movable with respect to the elongated shaft.” (Ex. 1001 at 14:53-54). The frame of reference for this limitation is the elongated shaft; the limitation requires both jaw members to move when viewed from that frame of

reference. Accordingly, there is no reasonable interpretation of claim 12 under which only one jaw of the claimed bipolar endoscopic forceps moves relative to the shaft and the other jaw is fixed relative to the shaft (*i.e.*, where the device has a “unilateral” design). Instead, the broadest reasonable interpretation requires both jaws to be movable with respect to the shaft (*i.e.*, the device has a “bilateral” design). This is further mandated by the recitation in claim 12 of “a handle attached to the drive rod assembly for imparting **movement of the first and second jaw members** between the first and second positions” and that both jaw members must be movable. (*Id.* at 14:53-54, 15:1-3).

This interpretation is consistent with the intrinsic record, in which all illustrated embodiments include bilateral jaws. (Ex. 1001 at Figs. 1-3, 5). When discussing jaw members 22 and 24, the ‘284 Patent refers to jaw members moving and to compression of jaw members about tissue. (*See, e.g., Id.* at 5:67-6:4, 6:60-61, 8:15-16, 8:28-29, 9:22-29, 10:15-16). Further, the mechanism that drives the jaws (described in incorporated-by-reference PCT App. No. PCT/US01/11340 (“*Dycus PCT*”), *see* Ex. 1001 at 6:20-27) only functions when “longitudinal reciprocation of the cam pin 170 rotates jaw members 110 and 120 about pivot pin 160 from the open to closed positions.” (Ex. 1010 at Figs. 7-8, 12, 22:5-6).

Thus, the broadest reasonable interpretation of this claim term requires that “both jaw members are movable with respect to the elongated shaft.”

B. “Drive Rod Assembly...”

Claim 12 requires a “drive rod assembly that connects the jaw members to a source of electrical energy.” (Ex. 1001 at 14:60-61). Claim 12 further requires “a handle attached to the drive rod assembly for imparting movement of the first and second jaw members between the first and second positions.”

Under the broadest reasonable interpretation of claim 12, the drive rod assembly, which is the structure that imparts movement on the jaws, must be specifically designed to carry electrical energy of the requisite first and second potentials to the jaw members. No reasonable interpretation of claim 12 covers a situation in which the component that imparts movement on the jaws simply encloses or houses another conductor that delivers electrical potential to the jaws.

The only uses of the word “connect” in the specification of the ‘284 Patent are in the electrical context, as opposed to a mechanical context. (*See* Ex. 1001 at 3:47-50, 3:57-61, 4:50-53, 5:7-8, 13:14-15). Moreover, claim 12 recites that the elongated shaft (not the drive rod assembly) provides the structural support for the “opposing jaw members,” which are “at a distal end thereof.” (*Id.* at 14:52-53). Thus, there is no embodiment of the ‘284 Patent wherein the drive rod assembly is not actually conducting electricity to the jaws of the bipolar endoscopic forceps. Nor should such an embodiment be covered under the broadest reasonable interpretation of this claim limitation. If PO presents a contrary argument that the

“drive rod assembly” can “connect” the jaws to sources of electrical potential in satisfaction of claim 12 simply by housing other conductors that carry electrical potential, Ground 5 shows that such arrangements were well-known.

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

Petitioner requests IPR of claims 1-18 based on the following grounds:

Ground	Statutory Basis	Relied-On Reference	Claims
1	35 U.S.C. § 103	<i>Fox</i> in view of <i>Eggers ‘142</i>	1-11
2	35 U.S.C. § 103	<i>Fox</i> in view of <i>Eggers ‘142</i> and <i>Slater</i>	11
3	35 U.S.C. § 103	<i>Eggers ‘471</i> in view of <i>Wales, Fox, and Eggers ‘142</i>	1-18
4	35 U.S.C. § 103	<i>Eggers ‘471</i> in view of <i>Wales, Fox, Eggers ‘142, and Slater</i>	11
5	35 U.S.C. § 103	<i>Schulze</i> in view of <i>Fox and Eggers ‘142</i>	12-18

A. Ground 1: Claims 1-11 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Fox* In View Of *Eggers ‘142*

1. Overview of the Prior Art

(a) *Fox*

Fox (Ex. 1006) was filed on September 29, 1995 and issued on October 7, 1997. (Ex. 1004 at ¶ 30). Accordingly, *Fox* is prior art under 35 U.S.C. § 102(b).⁴ It discloses a “bipolar coagulation device which may be used to grasp and treat tissue and may further include a cutting element to cut the treated tissue.” (Ex. 1006 at 2:62-65, *see also* Abstract, 3:45-53). *Fox*’s bipolar forceps includes an end effector which contains the jaws that grasp tissue for treatment. (*See, e.g., id.* at

⁴ Petitioner’s expert, David C. Yates, is a named inventor of *Fox*.

4:46-52). The device includes a closure tube 420, a handle 426, and a knife button 424 to close the jaws and actuate the knife. (*Id.* at 4:38-45; Ex. 1004 at ¶ 31).

In the Fig. 5 embodiment, jaw members 116 and 117 include flat tissue grasping surfaces 118 and 119. (Ex. 1006 at Fig. 5, 4:46-50; Ex. 1004 at ¶ 34). The jaws can include features, such as grasping teeth, to enhance the grasping. (Ex. 1006 at 5:33-40; Ex. 1004 at ¶ 33). In some embodiments, these grasping teeth may be rounded (*i.e.*, “they may have a radius...”). (Ex. 1006 at 5:42-43). Closure tube 115 “is adapted to close the jaws 116 and 117 together as tube 115 is advanced distally.” (*Id.* at 4:54-55). The jaws also include a knife channel and knife “adapted to cut tissue by moving distally in knife channel 143 when jaws 116 and 117 are closed to grip tissue.” (*Id.* at 5:17-19, 4:58-63; Ex. 1004 at ¶ 35).

Fox addresses the problem of shorting raised in the ‘284 Patent (Ex. 1001, 3:33-35), stating “[w]here necessary, shorting may be prevented by, for example, including an **island of insulation on the grasping surface 27 or 36 of either electrode 21 or 22 to establish an insulative gap** between the conductive surfaces.” (Ex. 1006 at 4:25-29; Ex. 1004 at ¶ 36). This disclosure is made with respect to Fig. 3, which, like Fig. 5, illustrates that the grasping surfaces 27 and 36 are flat surfaces. (Ex. 1006 at Fig. 3).

(b) *Eggers ‘142*

Eggers ‘142 (Ex. 1007) was filed on June 18, 1997 and issued on April 6,

1999. (Ex. 1004 at ¶ 41). *Eggers '142* is prior art under 35 U.S.C. § 102(b). It discloses bipolar electrosurgical forceps for use “in conjunction with conventional electrosurgical generators having bipolar outputs.” (Ex. 1007 at 5:65-67). “By applying bipolar, RF current from a noted electrosurgical generator across the outer working end tips of the forceps, a sealing or congealing of tissue or vessels can be achieved without substantial risk to adjacent tissue.” (*Id.* at 1:45-49).

Eggers '142 achieves “highly efficient hemostasis of grasped tissue or vessels” using “electrically insulative spacer regions” that “serve to space the tissue grasping surfaces apart an optimum distance, T, when substantially in a closed orientation.” (Ex. 1007 at 3:46-52). These can include “initial strips 124a and 126a at the respective ends or distal tip regions” of the forceps to “provide[] an initial ‘snagging’ geometry at the very tip of the forceps, a location most beneficial to achieve the requisite grasping function...” (*Id.* at 9:50-56; Ex. 1004 at ¶ 44). These spacer regions “are in substantially parallel relationship, and are aligned for movement into mutual contact when in a closed orientation...” (Ex. 1007 at 9:66-10:1). The spacers can be provided as a plurality of spacers running longitudinally from the distal end to the proximal end of the grasping surface (*id.* at 13:54-63, Fig. 15), an array of “spaced apart cubes” disposed in parallel linear arrays (*id.* at 14:19-22, Fig. 17), or an array of “discrete circular layers of thickness T” (*id.* at 14:46-48, Fig. 18). (Ex. 1004 at ¶ 45). *Eggers '142* discloses various materials

from which its spacers can be formed, including “electrically insulative glass, ceramic, or glass/ceramic pegs inserted within [] holes...” (Ex. 1007 at 14:56-59).

Eggers ‘142 discusses dimensions for its spacer regions that are very similar to the spacing disclosed in the ‘284 Patent. (*Compare* Ex. 1001 at 4:27-30 with Ex. 1007 at 10:56-11:24). A total distance, “T” between grasping surfaces is “established by the electrically insulative region” and represents the sum of the thicknesses T1 and T2 of the spacer regions on the two grasping surfaces. (Ex. 1007 at 10:59-61; Ex. 1004 at ¶ 48). T values between 0.020 and 0.001 inches are appropriate, although at the smaller end of the range (*i.e.*, under the minimum “practical” value of 0.003 inches), “arcing **may** occur.” (Ex. 1007 at 10:61-66; Ex. 1004 at ¶ 49). Accordingly, where T1 and T2 are equal, *Eggers* ‘142 discloses that individual spacers may extend from the grasping surfaces distances in the range of 0.010 inches to 0.0005 inches, with a minimum practical width of 0.0015 inches.

2. Motivation to Combine

A person of skill in the art would have been motivated to incorporate the spacer regions of *Eggers* ‘142 into the end effector illustrated in Fig. 5 of *Fox* as *Fox*’s disclosed islands of insulation to provide the benefits described in *Eggers* ‘142 in the *Fox* endoscopic bipolar forceps. (Ex. 1004 at ¶ 83; *see also* ¶¶ 84-89).

First, *Fox* and *Eggers* ‘142 both discuss “bipolar forceps” (*see, e.g.*, Ex. 1006 at 4:33; Ex. 1007 at 4:45-47), which constitutes a motivation to look to both

references when designing an improved bipolar forceps. The fact that *Eggers '142* illustrates its concepts in tweezers embodiments does not change its applicability to devices having the configuration of *Fox*; in both devices, flat seal surfaces are enhanced with insulative protrusions to prevent arcing, and the delivery of electrosurgical energy does not depend on the specific mechanism for applying closure force to the sealing surfaces. (Ex. 1004 at ¶¶ 56-57, 86). Nowhere does *Eggers '142* limit its disclosure to only tweezers-like devices. (*Id.* at ¶ 57). In fact, *Eggers '142* makes reference to relevant art in its background section that are explicitly directed to endoscopic bipolar forceps that are not tweezers. (*See, e.g.*, Ex. 1007 at 3:4-5 (*Eggers '471* and U.S. Patent No. 5,391,166 to one of the inventors of *Eggers '142*), 3:15 (Ex. 1013 naming Petitioner's expert David C. Yates as inventor), 3:30 (Ex. 1014, Petitioner's U.S. Patent No. 5,540,684); Ex. 1004 at ¶¶ 58-60). A person of skill in the art would have applied *Eggers '142*'s teachings of insulative spacers to any bipolar forceps device having appropriately shaped sealing surfaces, such as *Fox*. (Ex. 1004 at ¶¶ 56-61, 86, 88-89).

Moreover, *Fox* provides an express motivation to look to references like *Eggers '142* in discussing an "island of insulation" to establish an insulative gap. (Ex. 1006 at 4:25-29; Ex. 1004 at ¶ 84). *Fox* notes that such an island of insulation can be positioned on either electrode in a bipolar forceps device to prevent shorting or arcing during treatment. (*Id.*). A person of skill would have been motivated, in

view of this disclosure, to look to other references that disclose using similar insulative materials on similar tools for additional details on how the islands of insulation could be dimensioned, formed, and applied. (Ex. 1004 at ¶¶ 84-85). Accordingly, a person of skill in the art would have incorporated *Eggers '142's* teaching of dimensions (*see* Ex. 1007 at 10:46-11:24), material for (*id.* at 11:25-27) and arrangement of stop members on the sealing surfaces (*see, e.g., id.* at 9:2-23, Figs. 8, 10-13, 15, 17-18), and mechanisms for affixing stop members (*see, e.g., id.* at 11:25-45) to provide *Fox's* islands of insulation. (Ex. 1004 at ¶¶ 84-85).

Finally, *Fox* discloses embodiments in which the grasping benefits of *Eggers '142* are achieved with other features on the sealing surfaces of opposing electrodes of the forceps. *Fox* discloses that “[e]lectrodes 216 and 216 include tissue grasping teeth 206 and 208...” (Ex. 1006 at 5:36-37). These teeth are protruding features that facilitate better gripping of tissue. (Ex. 1004 at ¶¶ 87-89). A person of skill in the art would have understood that the spacers of *Eggers '142* are another example of protruding features that assist in the grasping of tissue. (Ex. 1007 at 3:59-62 (spacer regions “provide for an importantly improved grasping of tissue even though the exposed metal portions of the grasping surfaces are made to have smooth surfaces”); 9:45-58). Accordingly, *Eggers '142* discloses that its spacer regions can be provided on the sealing surfaces of an electrosurgical instrument (such as the Fig. 5 embodiment of *Fox*) to provide the grasping benefits

Fox discloses are achieved by its protrusions (*e.g.*, teeth of Fig. 7). (Ex. 1007 at 3:1-14; Ex. 1004 at ¶¶ 88-89). The proposed modification involves substituting surface features (*Fox*'s teeth) with another (*Eggers '142*'s spacers) to yield a predictable result (improved grasping).

Eggers '142's disclosure that one of the purposes of its disclosed spacers is to achieve the “originally desired grasping feature” (also described as a “snagging” performance) achieved using “a roughened or tooth-like surface” further confirms that its spacers can replace the teeth of a device like *Fox*. (Ex. 1007 at 3:1-3, 15:41-45, Figs. 20-21). This is particularly true since *Fox*'s discloses several kinds of surface features, including chamfered teeth, rounded teeth, and islands of insulation. (Ex. 1006 at 4:25-29, 5:36-43).

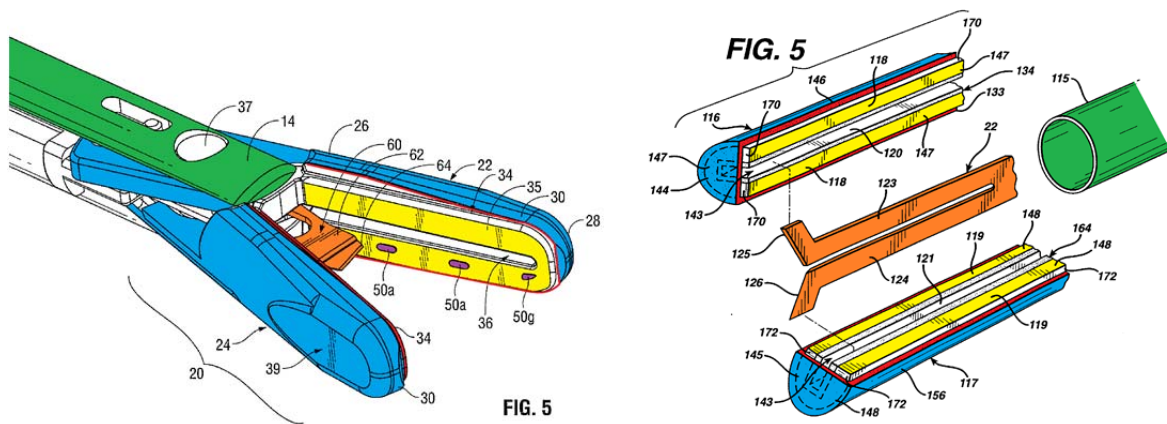
PO may also argue that the spacers of *Eggers '142* would not be incorporated along the entire length of *Fox*'s sealing surface. This argument lacks merit. *Eggers '142* teaches disposing its spacers along the grasping length L_G of the instrument, which may be as long as 1.2 inches. (Ex. 1007 at 10:29-31, 11:4-8, 14:25-32). *Fox* discloses a tissue stop 418, indicating that in *Fox*, tissue can be grasped anywhere in the length of the jaws. (Ex. 1006 at 4:38-39). Accordingly, the combination results in disposing *Eggers '142*'s spacers along the length of the grasping surfaces of, for example, *Fox*'s Fig. 5 end effector. (Ex. 1004 at ¶ 90).

For these reasons, the incorporation of *Eggers '142*'s spacer configurations

into Fig. 5 of *Fox* is an example of combining known elements according to known methods (as evidenced by the disclosure of *Fox*'s "island of insulation") to yield predictable results. The use of *Eggers '142*'s techniques for applying spacers (*see, e.g., Ex. 1007* at 11:25-35) is an example of using a known technique to improve similar devices disclosed in *Fox*. (*Ex. 1004* at ¶ 89). Thus, a person of skill in the art would have combined *Fox* with *Eggers '142* to provide the spacer regions of *Eggers '142* on the endoscopic bipolar forceps of *Fox*. (*Id.* at ¶¶ 83, 88-89).

3. Specific Identification of Challenge

Fig. 5 of the '284 Patent and Fig. 5 of *Fox* are reproduced below with color coding to indicate various common features of the '284 Patent and *Fox*'s device:



(*Ex. 1001* at Fig. 5; *Ex. 1006* at Fig 5). As described below, the one feature of the '284 Patent not depicted in Fig. 5 of *Fox* (*i.e.,* the stop members 50a, 50g in purple above) are nonetheless disclosed by *Fox*'s "island of insulation" and *Eggers '142*'s insulative spacers. (*See, e.g., Ex. 1006* at 4:25-29; *Ex. 1007* at Abstract).

(a) Claim 1

(i) Preamble

Claim 1 recites “[a]n endoscopic bipolar forceps.” *Fox* is directed to an endoscopic bipolar forceps and discloses the preamble. (*See* Ex. 1006 at Abstract (“bipolar endoscopic clamping, coagulation and cutting device”), 4:33-34).

(ii) Shaft/Jaw Members Limitations

Claim 1 requires “an elongated shaft having opposing jaw members at a distal end thereof, the jaw members...movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween.” *Fox* discloses the elongated shaft in the form of closure tube (element 420 of Fig. 4 and element 115 of Fig. 5, highlighted in green above) and opposing jaw members (elements 416 and 417 of Fig. 4 and elements 116 and 117 of Fig. 5, highlighted in blue above). (Ex. 1006 at 4:33-38, 4:54-55). In *Fox*, “[c]losure tube 115 is adapted to close the jaws 116 and 117 together as tube 115 is advanced distally.” (*Id.* at 4:54-55). Figs. 4 and 5 illustrate the jaw members in the first position. (*Id.* at Figs. 4-5). *Fox* also discusses that in the second position, the jaw members cooperate to grasp tissue. (*See, e.g., id.* at 2:62-3:2, 3:45-53 (“tissue 23 is grasped between first electrode 21 and second electrode 22), Fig. 3).

Claim 1 requires “the jaw members including a length and a periphery.” Figs. 4 and 5 of *Fox* illustrate that the jaw members (elements 416 and 417 of Fig.

4 and elements 116 and 117 of Fig. 5) each have a length extending generally along the axis of the closure tube (element 420 in Fig. 4 and element 115 in Fig. 5). Figs. 4 and 5 of *Fox* also illustrates that the jaw members include a periphery, illustrated by the portion in red in these figures. (*See* Ex. 1006 at Figs. 4 and 5).

Claim 1 requires “the jaw members each including respective flat seal surfaces extending along a respective length thereof.” In Fig. 5, *Fox* discloses the requisite flat seal surfaces in the form of “tissue grasping surfaces 118 and 119”, highlighted in yellow above (Ex. 1006 at 4:46-50, Fig. 5).

Claim 1 requires that the jaw members are “adaptable to connect to a source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal.” In *Fox*, the upper jaw 416 and the lower jaw 417 “are supported by upper wire form 414 and lower wire form 415. Wire forms 414 and 415 also act as conductors supplying bipolar electrical energy to upper jaw 416 and lower jaw 417 respectively.” (Ex. 1006 at 4:33-38). Similarly, jaw members 116 and 117 of Fig. 5 include electrodes 147 and 148. (*Id.* at 4:47-50). *Fox* describes the energy conducted in its system, stating “when an electrically conductive material such as organic tissue is grasped by the end effector, electrical current flows between first electrode 21 and second electrode 22.” (*Id.* at 3:50-53). It explains that this current flow “coagulat[es] the tissue.” (*Id.* at 3:58, *see also* Abstract, 1:6-9, 2:62-65, 4:15-21). This description of

treating by coagulating or cauterization discloses that *Fox* discloses a device that can “effectuate a tissue seal” as required by claim 1. Indeed, the ‘284 Patent admits that *Fox*’s device is capable of effecting a tissue seal. (Ex. 1001 at 3:7-10).

(iii) Plurality Of Stop Members Limitation

Claim 1 requires “a plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another.”

Fig. 5 of *Fox* illustrates an endoscopic bipolar forceps having jaws with flat seal surfaces annotated in yellow above. (Ex. 1006 at Fig. 5). *Fox* discloses that “[w]here necessary, shorting may be prevented by, for example, including an island of insulation on the grasping surface 27 or 36 of either electrode 21 or 22 to establish an insulative gap between the conductive surfaces.” (*Id.* at 4:25-29). Providing an island of insulation on the grasping surface of Fig. 5 results in a non-conductive stop member disposed on at least one of the seal surfaces of one of the jaw members. (Ex. 1004 at ¶ 37).

Eggers ‘142 discloses bipolar forceps having flat seal surfaces. (*See* Ex. 1007 at 6:23-25, 9:23-31 (numerals 120 and 122), Figs. 8-10). Similarly, Figs. 17 and 18 illustrate that sealing surfaces 204 and 128, respectively, are flat surfaces. (*Id.* at 14:25-29, 14:43-44). The embodiment illustrated in Figs. 8-10 of *Eggers*

'142 includes “electrically insulative spaced apart spacer regions which are mounted...upon both of the grasping surfaces 120 and 122.” (*Id.* at 9:33-36). It specifies that in this embodiment, the spacer regions are “evenly spaced apart longitudinally along a grasping length L_G .” (*Id.* at 9:40-42). These regions, labeled in Figs. 8-10 as 124a-124f and 126a-126f, disclose the claimed “plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another.” The “parallel linear arrays 212a-212c” of “electrically insulative spacer regions” disposed over the length L_G of Fig. 17 and the “regularly spaced linear arrays” of “electrically insulative spacer regions” of Fig. 18 are also examples of a “plurality of non-conductive stop members” having the geometry required by this claim limitation. (*Id.* at 14:19-29, 14:45-52).

As discussed above, *Fox's* disclosure of a tissue stop 418 (Ex. 1006 at 4:38) indicates that the entirety of *Fox's* end effector is intended to grasp tissue. (Ex. 1004 at ¶ 90). Incorporating the insulative spacers of *Eggers '142*, which are disposed along the entire grasping length L_G (Ex. 1007 at 10:29-31) results in spacers disposed along the length of *Fox's* seal surfaces and thus discloses non-conductive stop members having the required geometry. (Ex. 1004 at ¶ 90).

Claim 1 requires “the non-conductive stop members configured to maintain

a uniform distance between the jaw members along the length thereof.” *Fox* discloses that its “island of insulation” is provided to “establish an insulative gap” and to prevent shorting. (Ex. 1006 at 4:25-29). This is the same purpose as the stop members of the ‘284 Patent:

[T]o achieve a **desired spacing** between the electrically conductive surfaces 35 of the respective jaw members 22 and 24, (**i.e., gap distance**) and apply a desired force to seal the tissue 150, at least one jaw member 22 and/or 24 includes at least one stop member, e.g., 50a, which limits the movement of the two opposing jaw members 22 and 24 relative to one another.

(*Id.* at 10:52-58). *Fox*’s disclosed stop members create a uniform desired gap distance the same way as the ‘284 Patent. Especially because *Fox* is a parallel closure device (*i.e.*, driven by a closure tube rather than pivoting) and its jaws are parallel to each other **as they close**, and not just **at the point of closure**, (*see, e.g.*, Ex. 1001 at Figs. 1-2, Ex. 1004 at ¶ 38), the use of a stop member to set an insulative gap means that when the jaws are closed to a point of touching the island of insulation, the jaws are parallel and the gap is uniform. (Ex. 1004 at ¶ 38).

The particular arrangement of insulative spacers in *Eggers* ‘142 also provides for the claimed “uniform distance between the jaw members”; this distance is referred to in *Eggers* ‘142 as “T”. (*See, e.g.*, Ex. 1007 at 10:56-59). In the Figs. 8-10 embodiment of *Eggers* ‘142, spacers are selected having a thickness T1 along one grasping surface 120, and having a thickness T2 along a second

grasping surface 122. (*Id.* at 9:37-50). *Eggers '142* specifies that the strips are “aligned for movement into mutual contact when in a closed orientation.” (*Id.* at 9:66-10:1). *Eggers '142* discloses with regard to Fig. 11 that “[u]pon further pressure being made by the user, then the remaining strips progressively come into contact.” (*Id.* at 10:54-56, Fig. 11). The distance between the sealing surfaces when such contact is made by the “further pressure” is the above-noted “T”. (*Id.* at 10:58-59). In this situation, the distance “T” between the sealing surfaces is uniform along the length because the thicknesses of the spacer regions (*i.e.*, “T1” and “T2”) are constant. (*Id.* at 10:56-11:8, Ex. 1004 at ¶¶ 46-47).⁵

Further, “[t]he thickness’ T1 and T2, inter alia, are selected such that the tissue or vessel media is extruded into the recesses between the strips 124a-124f and 126a-126f to assure electrical contact with the smooth grasping surfaces as at 120 and 122 located intermediate the strips.” (Ex. 1007 at 10:2-6). This disclosure

⁵ PO will likely argue that the distance between the sealing surfaces of Fig. 11 is not “uniform.” (*See, e.g.*, Ex. 1002 at pp. 718-19). This is incorrect. The spacers of *Eggers '142* only maintain distance between sealing surfaces when they are all contacting one another; otherwise, the amount of pressure applied by the user controls spacing. (Ex. 1004 at ¶¶ 46, 47). Fig. 11 illustrates a point before “further pressure” is applied. (Ex. 1007 at 10:54-56. With “further pressure,” the spacers all come into contact and the gap distance is uniform. (*Id.*)

teaches that when tissue is grasped in the *Eggers '142* device, its shape adapts into that illustrated in Figs. 8-9, wherein the tissue is uniformly thick across the grasping surface. Accordingly, to the extent the claimed stop members must define, in part, the distance between sealing surfaces when tissue is grasped therebetween, Figs. 8-9 of *Eggers '142* illustrate the requisite uniform distance.

Accordingly, when the plurality of stop members from *Eggers '142* are incorporated into *Fox*, they are configured to maintain a uniform distance (*i.e.*, gap distance) between the jaw members along a length thereof.

(iv) Knife Limitation

Claim 1 requires “a knife disposed in operative communication with at least one of the jaw members and translatable to sever tissue disposed between jaw members.” *Fox* discloses the required knife for performing the required severing of tissue: “knife 122 is adapted to cut tissue by moving distally in knife channel 143 when jaws 116 and 117 are closed to grip tissue.” (Ex. 1006 at 5:17-19, Fig. 5; *see also* 6:60-63). Movement of *Fox*’s knife in a knife channel discloses the claimed operative communication with at least one of the jaw members. (*Id.*)

(b) Claim 2

Claim 2 depends from claim 1 and requires that “the forceps includes at least two non-conductive stop members disposed on the inner facing surface of at least one of the jaw members that extend different heights from the inner facing

surface.” Petitioner submits that this claim limitation is (a) not supported by the disclosure of the ‘284 Patent and (b) at odds with the requirement of claim 1 (and PO’s arguments during prosecution) that “the non-conductive stop members [are] configured to maintain a **uniform distance** between the jaw members along the length thereof.” Providing stop members of different heights as required by this claim necessarily results in a non-uniform distance between jaw members.

To the extent this limitation is disclosed by the ‘284 Patent and is not at odds with the requirements of claim 1, the only reasonable interpretation of this limitation is that due to manufacturing tolerances, the stop members *necessarily* have at least some difference in height. Under this interpretation, at least the Fig. 18 embodiment of *Eggers ‘142*, in which the stop members are formed by inserting pegs into holes, manufacturing tolerances associated with formation of the pegs and formation of the holes would likewise result in stop members having slightly different heights above the sealing surface 218. (Ex. 1007 at 14:41-59, Fig. 18). *Eggers ‘142* therefore discloses stop members having differing heights to the same extent as the ‘284 Patent discloses that concept.

Alternatively, if this claim is read as covering stop members having intentionally different heights (which is not supported by the ‘284 Patent), *Eggers ‘142* discloses this arrangement, as it discloses that “spacing, T, represents the sum of the thickness’ T1 and T2 for the instant embodiment.” (Ex. 1007 at 10:59-61,

see also claim 10). A person of skill in the art would understand that T1 can be equal to T2 (and thus each height is 1/2 of the spacing “T”), or T1 and T2 can be different and nonetheless sum to total thickness T. (*See id.* at claim 10, Ex. 1004 at ¶¶ 50-53). Accordingly, incorporating the stop members of Figs. 8, 17, or 18 of *Eggers ‘142* into the end effector of Fig. 5 of *Fox* discloses this claim limitation when T1 and T2 are different for a pair or pairs of stop members.

(c) Claim 3

Claim 3 depends from claim 1 and requires that “at least one of the jaw members includes an electrically conductive surface having a longitudinally-oriented channel defined therein which facilitates longitudinal translation of the knife for severing tissue.” *Fox* illustrates a longitudinally-oriented channel (knife channel 143 of Fig. 5). (Ex. 1006 at 4:57-60, *see also* 3:5-11, 5:17-19, Fig. 5).

(d) Claim 4

Claim 4 depends from claim 3 and further requires that “at least one non-conductive stop member is disposed on the electrically conductive surface of the jaw member proximate one side of the longitudinally-oriented channel and at least one non-conductive stop member is disposed on the electrically conductive surface of the jaw member proximate another side of the longitudinally-oriented channel.” In the embodiments of *Eggers ‘142* where a plurality of discrete spacer regions are positioned in an array form, the array has two dimensions, arranged as “three

parallel linear arrays” across the width of the grasping surface. (See Ex. 1007 at Figs. 17, 18, 14:19-22, 14:45-52). In *Fox*, the sealing surfaces of Fig. 5 are on either side of the channel 143 (Ex. 1006 at 4:57-60, *see also* 3:5-11, 5:17-19, Fig. 5), and in embodiments with grasping features (*i.e.*, teeth), the grasping features are likewise on either side of the channel. (Ex. 1006 at Fig. 7, 5:33-40; Ex. 1004 at ¶¶ 39-40). Accordingly, when the stop members of *Eggers* ‘142 are incorporated as the grasping features of *Fox*, the middle linear array of features of Figs. 17 and 18 of *Eggers* ‘142 is removed to accommodate *Fox*’s channel, leaving the outer arrays of features of *Eggers* ‘142. (Ex. 1004 at ¶¶ 39-40, 89). This results in stop members disclosed on both sides of the longitudinally-oriented channel. (*Id.*).

(e) Claim 5

Claim 5 depends from claim 1 and requires that “the non-conductive stop members are manufactured from the group consisting of: parylene, nylon and ceramic.” *Eggers* ‘142 discloses that its spacer regions can be formed of ceramic, and thus discloses this dependent claim. (Ex. 1007 at 11:25-35, 14:56-59).

(f) Claim 6

Claim 6 depends from claim 1 and requires that “the non-conductive stop members include a series of longitudinally-oriented projections that extend from a proximal end of the jaw member to a distal end of the jaw member.” Both the Fig. 15 embodiment and the Fig. 17 embodiment of *Eggers* ‘142 disclose the

arrangement of stop members required by this dependent claim.

In the Fig. 15 embodiment of *Eggers '142*, “the electrically insulative spaced apart spacer regions are formed, for instance, as an array of parallel strips 196a-196c which are generally aligned with the axis 194 and extend outwardly to the periphery 198 of the nose portion of the tine 190.” (Ex. 1007 at 13:59-63, Fig. 15). In the combination relied on herein, these strips 196a to 196c are “a series of longitudinally-oriented projections” and extend from the proximal to the distal end of the seal surfaces when incorporated into *Fox*. (See Ex. 1004 at ¶ 90).

Fig. 17 of *Eggers '142* also discloses a series of longitudinally oriented spacers by its disclosure of parallel linear arrays of spacers. It discloses forming such spacers by depositing a layer of insulative material over the whole grasping surface L_G and grinding off those portions where the spacers are not to be provided. (Ex. 1007 at 14:25-32). In Fig. 17, this grinding is both longitudinal (*i.e.*, along the axis of the device to form the three rows of spacers) and across the device (to form the seven columns of spacers). Because *Eggers '142* discloses that the result of these operations can be either cubes (as illustrated in Fig. 17) or “electrically insulative rectangles” (*id.* at 14:20-22, 14:31-32), *Eggers '142* discloses both the Fig. 17 embodiment and an embodiment wherein fewer vertical grinding operations results in rectangles that are longer in the longitudinal direction than they are in the direction across the instrument. Indeed, *Eggers '142* discloses

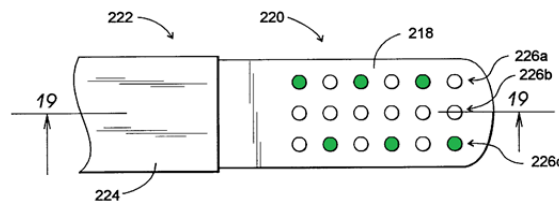
that this process can be used to create the longitudinal spacers of Fig. 15 (*i.e.*, in a situation where **zero** vertical grinding operations are performed). (*Id.* at 14:32-34). Incorporating this embodiment of *Eggers '142* into *Fox* also results in the requisite stop members along the length of the jaw members. (*See* Ex. 1004 at ¶ 90).

(g) Claim 7

Claim 7 depends from claim 1 and requires that “the non-conductive stop members include a series of circle-like tabs which extend from a proximal end of the jaw member to a distal end of the jaw member.” Fig. 18 of *Eggers '142* discloses the required circular tabs along the sealing surface L_G , and when incorporated in Fig. 5 of *Fox*, these tabs are disposed from the proximal to the distal end of the jaw members. (Ex. 1007 at 14:45-59, Fig. 18; Ex. 1004 at ¶ 90).

(h) Claim 8

Claim 8 depends from claim 7 and requires “that the circle-like tabs are disposed in an alternating, laterally-offset manner relative to one another along a length of the jaw member.” This claim is a comprising claim, so at least the green highlighting in the below version of Fig. 18 of *Eggers '142* illustrates that the array of circle-like tabs disclosed therein contains the requisite geometry:



(Ex. 1007 at Fig. 18, 14:45-59).

(i) Claim 9

Claim 9 depends from claim 1 and requires that “the non-conductive stop members each protrude about 0.001 inches to about 0.005 inches from the inner facing surface of the jaw member.” *Eggers ‘142* discloses preferred values of T (*i.e.*, the total spacing between sealing surfaces) of between 0.020 inches and 0.003 inches, with workable values of T as small as 0.001 inches. (Ex. 1007 at 10:56-64; Ex. 1004 at ¶ 49). Accordingly, in the Figs. 8-10 embodiments of *Eggers ‘142*, where “T” is the sum of the heights “T1” and “T2” of the upper and lower spacers, respectively (Ex. 1007 at 10:59-61), the disclosed stop members preferably protrude between 0.010 inches and 0.0015 inches with workable values as small as 0.0005 (*i.e.*, half the disclosed range of “T”) from the inner facing surfaces. (*Id.* at 10:56-64, Ex. 1004 at ¶¶ 49-50). This discloses the claimed range.

(j) Claim 10

Claim 10 depends from claim 1 and requires that “the non-conductive stop members each protrude about 0.002 inches to about 0.003 inches from the inner facing surface of the jaw member.” As discussed with regard to claim 9, *Eggers ‘142* discloses values of T between 0.020 inches and 0.003 inches and therefore heights of stop members from the inner-facing sealing surfaces of between 0.010 inches and 0.0015 inches (*i.e.*, half the disclosed range of “T”). (Ex. 1007 at 10:56-64, Ex. 1004 at ¶¶ 49-50). This substantially overlaps the claimed range.

(k) Claim 11

Claim 11 depends from claim 1 and requires that “the non-conductive stop members are affixed to the jaw member by a molding process.” Importantly, the ‘284 Patent does not provide any reason to ascribe patentable weight to the recitation of “molding” as a technique to manufacture stop members. (Ex. 1004 at ¶¶ 24-25). *Eggers ‘142* nevertheless discloses many mechanisms for affixing stop members to sealing surfaces of a bipolar forceps device. (See, e.g., Ex. 1007 at 11:25-35, 14:36-40). At least one process involves inserting the stop member structures into appropriate openings in the sealing surfaces. (*Id.* at 14:56-59). *Eggers ‘142* further discloses the advantages of using an “insert molding manufacturing process as a means to reduce the cost of manufacture.” (*Id.* at 19:12-14). Accordingly, *Eggers ‘142* discloses that molding processes can be used in fabricating bipolar forceps devices, particularly to add insulative material to metal surfaces. (Ex. 1004 at ¶¶ 54-55). This teaching combined with teaching filling holes with spacers to form insulative spacers discloses this dependent claim.

B. Ground 2: Claim 11 Is Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Fox* In View Of *Eggers ‘142* and *Slater*

1. Overview of the Prior Art

(a) *Slater*

Slater (Ex. 1011) was filed on August 17, 1993 and issued on March 14, 1995, and is thus prior art under 35 U.S.C. § 102(b). It discloses a “non-metallic

end effector for use in an endoscopic surgical tool...” (Ex. 1011 at Abstract). Citing the notion that “end effectors are difficult to manufacture and are typically formed of forged stainless steel,” (*id.* at 1:51-53), *Slater* notes that its end effector is “formed of both conductive material and non-conductive material; the non-conductive material surrounding all of the conductive material but for a selected electrode surface and a selected surface for coupling with an electrical source.” (*Id.* at 3:22-26). “In order to provide a selected conductive surface within the working surface 202 and to strengthen the end effector 290, a metal spine 204 is insert molded in the non-conductive material of which the end effector is made.” (*Id.* at 5:34-38). *Slater* thus discloses injection molding to form end effectors of electrosurgical devices with well defined configurations of conductive/non-conductive surfaces. (*Id.* at 5:53-55, 5:64-65, 8:29-9:2; Ex. 1004 at ¶¶ 78-82).

2. Motivation to Combine

A person of ordinary skill in the art would have been motivated to use the end effector manufacturing techniques of *Slater* to manufacture the end effector resulting from the combination of *Fox* and *Eggers '142* discussed in Ground 1. (Section VIII.A.2; Ex. 1004 at ¶¶ 91-98). Specifically, *Eggers '142*'s discussion of the economic benefits of using molded plastic to form insulative features of bipolar forceps (Ex. 1007 at 19:10-14) is a motivation to look to other references discussing the feasibility of using molded plastic in end effectors of bipolar forceps

instruments. (*See, e.g.*, Ex. 1011 at 5:32-38; Ex. 1004 at ¶¶ 94, 96). A person of skill in the art would have been motivated to use *Slater*'s injection molding techniques to provide the stated "very well defined conductive surface" by using injection molding techniques, (Ex. 1011 at 5:51-55) to form the insulative features of *Eggers '142*, which also result in very well defined conductive (and, therefore, insulative) surfaces. (Ex. 1007 at 14:25-40, 14:48-59, Figs. 17-18; Ex. 1004 at ¶¶ 92-94, 96-97). Because *Fox* discusses islands of insulation without providing specific manufacturing techniques, a person of skill in the art would have been motivated to locate art like *Slater*, which confirms that injection molding is one way to precisely define the non-conductive surfaces of the end effector of a bipolar forceps device. (Ex. 1006 at 4:25-29; Ex. 1004 at ¶¶ 95-96). *Slater* itself discloses the applicability of its techniques to a broad range of devices. (*See, e.g.*, Ex. 1011 at 5:62-65, 7:22-32, 8:37-56). Because there are a finite number of manufacturing techniques to form stop members, *Slater*'s techniques are obvious to try and carry with them a reasonable expectation of success.

3. Specific Identification of Challenge

(a) Claim 11

Eggers '142 discloses including inserting stop member structures into openings on a sealing surface. (Ex. 1007 at 11:25-35, 14:36-40). It also discloses the advantages of using an "insert molding manufacturing process as a means to

reduce the cost of manufacture.” (*Id.* at 19:12-14). *Slater* confirms that injection molding can be used to form end effectors with “very well defined” insulative surfaces. (Ex. 1011 at Abstract, 2:37-40, 3:22-26, 5:34-39, 5:51-55, 5:62-65). Accordingly, the combination discloses that the non-conductive stop members are affixed to the jaw member by a molding process. (Ex. 1004 at ¶¶ 96-97).

C. Ground 3: Claims 1 to 18 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Eggers ‘471, Wales, Fox, and Eggers ‘142*

1. Overview of the Prior Art

(a) *Eggers ‘471*

Eggers ‘471 (Ex. 1009) issued on July 19, 1994, and is prior art under 35 U.S.C. § 102(b). It discloses “bipolar electro-surgical instruments for hemostatically severing or manipulating tissue in endoscopic surgical procedures.” (Ex. 1009 at 3:36-39). Such instruments can include “any of a variety of severing or grasping members at its working end” including a dissector embodiment having jaw-like members. (*Id.* at 6:1-4, 6:13-15, 10:31-45, 11:32-45, Figs. 7A-7B; Ex. 1004 at ¶¶ 67-68). Actuation is by a “[d]rive rod 16 disposed in elongated barrel 15 [that] has electrical terminals 17 that are connected to movable members 18 and 19 of working end 11 to provide an electrical potential therebetween.” (Ex. 1009 at 6:22-25; Ex. 1004 at ¶¶ 70-71). Drive rod 16 includes halves 16’ separated by “layer 45 of insulating material disposed on contacting surfaces 44, so that no current passes through those contacting surfaces.” (Ex. 1009 at 7:43-51; Ex. 1004

at ¶ 69). “[T]he electrical circuit energizing each bipolar electrode extends from electrical terminals 17 on the proximal portion 30 of drive rod 16, through halve 16’ of drive rod 16 to proximal portion 31 of halve 16’.” (*Id.* at 10:5-9).

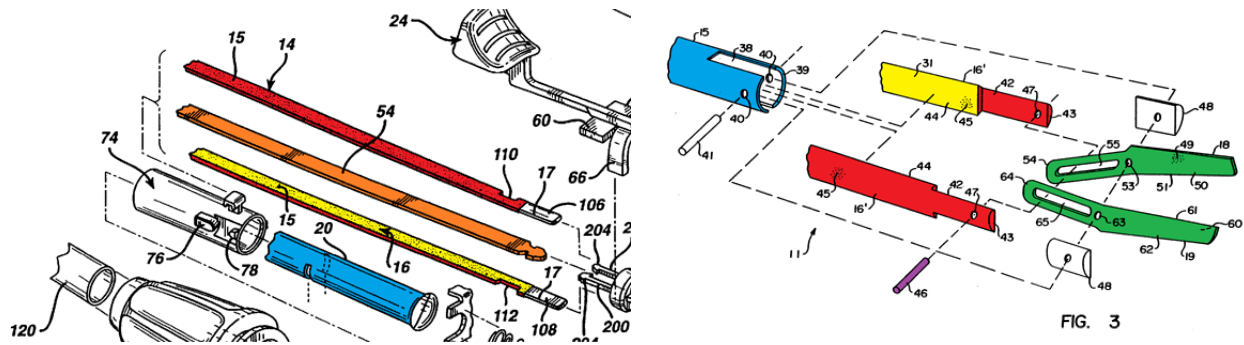
(b) *Wales*

Wales (Ex. 1008), which is directed to a device similar to that disclosed in *Fox* (Ex. 1004 at ¶¶ 62-63, 66, 74), issued on September 1, 1998. It is prior art under 35 U.S.C. § 102(b). *Wales* discloses that “[w]ire forms 14 and 16 may [] act as electrical conductors, supplying bipolar electrical energy to end effector 12.” (Ex. 1008 at 3:48-50; Ex. 1004 at 64). With regard to Figs. 5 and 6, *Wales* states that “[w]ireforms 14 and 16 each include insulation layer 15 and an electrical conductor 17” (Ex. 1008 at 4:27-28), where the knife “may be moved axially independent of wireforms 14 and 16 of end effector 12 while the [knife] moves rotationally in conjunction with wireforms 14 and 16 and with end effector 12” (*id.* at 4:62-65). *Wales* relies on a closure tube 20 to “force wireforms 14 and 16 together, forcing the jaws of end effector 12” together to a closed position where “end effector 12 is adapted to grasp tissue 40.” (*Id.* at 3:64-4:1). “Movement of knife button 24 in direction B1 moves knife 42 out of tissue stop 18 in direction B2. Movement of knife 42 in direction B2 cuts tissue positioned in end effector 12.” (*Id.* at 4:6-9).

2. Motivation to Combine

As discussed above in Section VIII.A.2 above, a person of skill in the art would have been motivated to combine *Eggers '142* with *Fox* at least because *Fox's* discussion of islands of insulation constitutes a motivation to look to *Eggers '142's* teaching regarding spacers. In addition to sharing inventors, *Eggers '142* also specifically refers to *Eggers '471* (*see* Ex. 1007 at 3:1-14), and thus provides a motivation to look to *Eggers '471*. (Ex. 1004 at ¶ 100). This along with *Eggers '142's* other references to patents disclosing bipolar endoscopic instruments (*see* Ex. 1007 at 3:4-5, 3:15, 3:30), more generally motivates those of skill in the art to look to art disclosing bipolar endoscopic forceps having jaws disposed at the distal end of a shaft, such as *Wales*, *Fox*, and *Eggers '471*, when considering the stop member-related teachings of *Eggers '142*. (Ex. 1004 at ¶ 100). The similarity of *Fox* and *Wales* indicates that a person of skill would have looked to *Fox* regarding, for example, its discussion of an end effector and knife, and would have looked to *Wales* for its discussion of the mechanical apparatus within the instrument to cause the end effector to close and the knife to be actuated. (Ex. 1004 at ¶ 101).

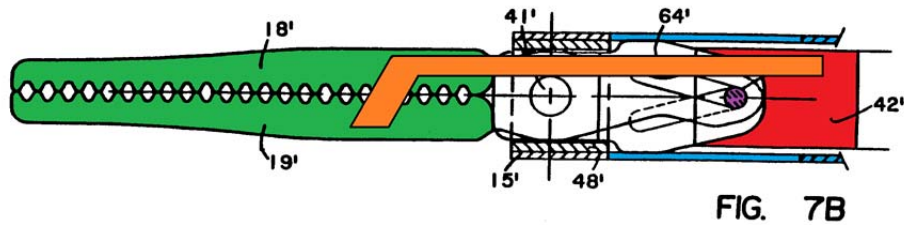
In general, those of skill are motivated to try to include as many surgical capabilities as possible in a single device. (Ex. 1004 at ¶¶ 102, 107-109). Motivated by this general design principal, a person of skill in the art would have understood to combine *Wales* and *Eggers '471* as illustrated and discussed below:



(Ex. 1008 at Fig. 5; Ex. 1009 at Fig. 3; Ex. 1004 at ¶¶ 64-65, 69). Each device includes an outer shaft, highlighted in blue, which houses mechanical and electrical components. (Ex. 1008 at 3:50-52; Ex. 1009 at 6:19-22). Each device includes a pair of internal conductive structures (highlighted in red) for delivering electricity to the end effector (highlighted in green). (Ex. 1008, 3:48-50; Ex. 1009 at 6:22-25, 10:5-14). The pair of internal conductive structures in each device is coated with an insulative material (highlighted in yellow) to prevent electricity from flowing between the two structures. (Ex. 1008 at 7:49-51, Ex. 1009 at 7:6-9, 10:14-19). *Wales* discloses that with this arrangement of conductors coated in insulative material for delivering electrical potential to an end effector, a knife drive mechanism (highlighted in orange) including a knife at the distal end thereof can be disposed between the conductors such that the knife drive mechanism/knife can move independently of the conductors. (See, e.g., Ex. 1008 at 4:49-52).

A person of skill would understand that combining *Wales* and *Eggers* '471 results in a device wherein the two halves 16' of the drive rod assembly 16 of *Eggers* '471 could both deliver electrical potential to the end effector and drive the

jaws of the end effector closed, as in *Eggers '471*, and the knife push rod 54 and knife 42 of *Wales* could be disposed between halves 16' as an independently actuated knife within the volume of the shaft. (Ex. 1004 at ¶¶ 103-105). The end effectors would include knife channels, and the knife would be shaped like the bottom half of the knife of *Fox*, enabling it to slide as needed while avoiding the pivot of *Eggers '471*. (Ex. 1004 at ¶ 106). The following figure illustrates this:



A person of skill in the art, having combined *Fox's* Fig. 5 end effector with *Eggers '142's* configurations of insulative spacers as discussed above, would also have been motivated to look to *Wales* and *Eggers '471* for detail about the mechanisms within the shaft of the combined instrument that allow for *Fox's* end effectors to close and to also reciprocate a knife therethrough. (Ex. 1004 at ¶¶ 99, 110).

3. Specific Identification of Challenge

As described in detail below, the combination of references supporting this Ground renders claims 1-18 of the '284 Patent obvious under a claim interpretation where the drive rod assembly of claim 12 must be specifically designed to carry electrical energy of the requisite first and second potentials to the jaw members. It also renders claims 1-18 obvious under broader interpretations of claim 12.

(a) Claim 1

(i) Preamble

Fox, *Wales*, and *Eggers '471* all disclose endoscopic bipolar forceps as required by the preamble. (See Ex. 1006 at Abstract, 4:33-34; Ex. 1008 at Fig. 1, 3:44-45; Ex. 1009 at Abstract, Figs. 7A-7B, 6:1-4, 11:32-34).

(ii) Shaft/Jaw Members Limitations

Fox discloses the requisite elongated shaft and opposing jaw members movable from a first position to a second position as described in Ground 1. (Section VIII.A.3(a)(ii); see Ex. 1006 at 2:62-3:2, 3:45-53, 4:33-38, 4:54-55, Figs. 3-5). *Wales* likewise discloses a shaft in the form of closure tube 20, highlighted in blue above. (See Ex. 1008 at 3:50-55, Fig. 1, Fig. 5). In *Wales*, jaws 214 and 216 are at the distal end of the closure tube 20 and are movable from a first position to a second position to grasp tissue. (*Id.* at 3:45-48, 3:61-4:3, Figs. 1-3). *Eggers '471* discloses a shaft (elongated barrel 15) with “electrical terminals 17 that are connected to movable members 18 and 19 of working end 11...” (Ex. 1009 at 6:19-25). The movable members, which can be “jaw-like members 18’ and 19’,” move as required. (*Id.* at 11:32-36, 11:47-54, 12:13-19, Figs. 7A-7B).

At least the jaw members of Fig. 5 of *Fox* have the requisite length, periphery, and flat seal surfaces. (Section VIII.A.3(a)(ii); see also Ex. 1006 at Fig. 4, elements 416 and 417, Fig. 5, elements 11 and 117, 4:48-50).

Fox, *Wales*, and *Eggers '142* disclose jaw members connected to a source of

electrical energy as required. (Section VIII.A.3(a)(ii); *see also* Ex. 1006 at 3:58, Abstract, 1:6-9, 2:62-65, 4:15-21, 3:50-53, 4:33-38, 4:47-50; Ex. 1001 at 3:7-10; Ex. 1008 at 1:52-54, 3:48-50; Ex. 1009 at 1:64-2:11, 4:47-51, 12:2-4).

(iii) Plurality Of Stop Members

The combination of *Fox* and *Eggers '142* discloses the stop members on flat seal surfaces as required by claim 1. (Section VIII.A.3(a)(iii); *see* Ex. 1006 at Fig. 5, 4:25-29; Ex. 1007 at 6:23-25, 9:23-31, 9:33-36, 9:40-42, 14:25-29, 14:19-29, 14:43-52). When the electrically insulative spacers of *Eggers '142* are incorporated as *Fox's* islands of insulation, the combination discloses the claimed plurality of non-conductive stop members.

Claim 1 requires “the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof.” As described above, the incorporating *Eggers '142's* spacers into the end effector of *Fox* discloses this limitation. (Section VIII.A.3(a)(iii)). Specifically, *Fox* discloses that its “island of insulation” is provided to “establish an insulative gap” (much like the '284 Patent) and to prevent shorting, and thus discloses the claimed “uniform distance between the jaw members along the length thereof.” (Ex. 1006 at 4:25-29; Ex. 1004 at ¶ 38). This is particularly true in view of *Fox* being a parallel closure device. (*Id.*) *Eggers '142's* discussion of the distance “T” discloses the requisite “uniform distance between the jaw members.” (*See, e.g.,*

Ex. 1007 at 9:37-50, 9:59-60, 10:56-59, Figs. 8-10). *Eggers '142* specifies that the strips are “aligned for movement into mutual contact when in a closed orientation,” (*id.* at 9:66-10:1), and that “[u]pon further pressure being made by the user, then the remaining strips progressively come into contact.” (*Id.* at 10:54-56). The distance between sealing surfaces when “further pressure” is applied is labeled “T”. (*Id.* at 10:58-59). Therefore, distance “T” is the requisite uniform distance between sealing surfaces. (Ex. 1007 at 10:54-11:8, Ex. 1004 at ¶¶ 46-47).

Eggers '142 teaches that that when tissue is grasped, its shape adapts until the tissue is uniformly thick across the grasping surface. (*Id.* at 10:2-6). To the extent the spacers of *Eggers '142* define, in part, the distance between sealing surfaces when tissue is grasped, Figs. 8-9 illustrate that the tissue changes its shape based on the applied pressure to result in uniform distance between the sealing surfaces of the bipolar forceps. (Ex. 1007 at Figs. 8-9).

Accordingly, when the plurality of stop members from *Eggers '142* are incorporated into *Fox*, they are configured to maintain a uniform distance (*i.e.*, gap distance) between the jaw members along a length thereof.

(iv) Knife Limitation

Fox discloses the required knife for severing tissue. (Ex. 1006 at 5:17-19, Fig. 5, 6:60-63). *Wales* also discloses a push bar 54 connected to knife 42 that can be actuated by knife button 24. (Ex. 1008 at 4:4-9, 4:17-19, 4:23-30, 4:4:55-65).

(b) Claim 2

Claim 2 depends from claim 1 and relates to the particular arrangement of stop members. As discussed above, *Fox* and *Eggers '142* disclose the additional limitations of claim 2 to the extent they are enabled. (Section VIII.A.3(b); Ex. 1007 at 10:59-61, 14:41-59, Fig. 18, claim 10; Ex. 1004 at ¶¶ 50-53).

(c) Claim 3

Claim 3 depends from claim 1 and relates to the particular arrangement of stop members on the jaws of the forceps. As discussed above with regard to Ground 1, *Fox* and *Eggers '142* disclose the additional limitations of claim 3. (Section VIII.A.3(c); Ex. 1006 at 4:57-60, *see also* 3:5-11, 5:17-19, Fig. 5).

(d) Claim 4

Claim 4 depends from claim 3 and relates to the particular arrangement of stop members on the jaws of the forceps. As discussed with regard to Ground 1, *Fox* and *Eggers '142* disclose the additional limitations of claim 4. (Section VIII.A.3(d); Ex. 1007 at 10:26-29, 14:19-22, 14:45-52, Figs. 10, 17, 18; Ex. 1006 at 3:5-11, 5:33-40, 4:57-60, 5:17-19, Figs. 5, 7; Ex. 1004 at ¶¶ 39-40, 89).

(e) Claim 5

Claim 5 depends from claim 1 and relates to materials. *Eggers '142* discloses these materials. (Section VIII.A.3(e); Ex. 1007 at 11:25-35, 14:56-59).

(f) Claim 6

Claim 6 depends from claim 1 and relates to the arrangement of stop

members. *Fox* and *Eggers '142* disclose these limitations. (Section VIII.A.3(f); Ex. 1004 at ¶ 90; Ex. 1007 at 13:59-63, 14:20-22, 14:25-34, Fig. 15, Fig. 17).

(g) Claim 7

Claim 7 depends from claim 1 and relates to the arrangement of stop members. As discussed above, *Fox* and *Eggers '142* disclose claim 7's additional limitations. (Section VIII.A.3(g); Ex. 1007 at 14:45-59, Fig. 18; Ex. 1004 at ¶ 90).

(h) Claim 8

Claim 8 depends from claim 7 and relates to the arrangement of stop members on the jaws. As discussed above, *Fox* and *Eggers '142* disclose claim 8's additional limitations. (Section VIII.A.3(h); Ex. 1007 at Fig. 18, 14:45-59).

(i) Claim 9

Claim 9 depends from claim 1 and relates to the arrangement of stop members. As discussed above, *Fox* and *Eggers '142* disclose claim 9's additional limitations. (Section VIII.A.3(i); Ex. 1007 at 10:56-64, Ex. 1004 at ¶¶ 49-50).

(j) Claim 10

Claim 10 depends from claim 1 and relates to the particular arrangement of stop members. *Fox* and *Eggers '142* disclose claim 10's additional limitations. (Section VIII.A.3(j); Ex. 1007 at 10:56-64; Ex. 1004 at ¶¶ 49-50).

(k) Claim 11

Claim 11 depends from claim 1 and relates to the technique for manufacturing stop members. As discussed with regard to Ground 1, *Fox* and

Eggers '142 disclose the additional limitations of claim 11. (Section VIII.A.3(k); Ex. 1007 at 11:25-35, 14:36-40, 14:56-59, 19:12-14; Ex. 1004 at ¶¶ 24-25, 54-55).

(I) Claim 12

(i) Preamble

Claim 12 is directed to “[a]n endoscopic bipolar forceps.” *Fox, Wales*, and *Eggers '471* all disclose the preamble. (Ex. 1006 at Abstract, 4:33-34; Ex. 1008 at Fig. 1, 3:44-45; Ex. 1009 at Abstract, Figs. 7A-7B, 6:1-4, 11:32-34).

(ii) Shaft/Jaw Members Limitations

Claim 12 requires “at least one elongated shaft having opposing jaw members at a distal end thereof, the jaw members movable with respect to the elongated shaft, the jaw members having a length and movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween.” It also requires “the jaw members each including respective flat seal surfaces extending along a respective length thereof such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal.” These limitations of claim 12 are nearly identical limitations as those imposed in claim 1. Claim 12 is broader in that the jaw members need not include a periphery, and narrower in that the jaw members of claim 12 must be “movable with respect to the elongated shaft.”

As described with regard to claim 1, *Fox, Wales*, and *Eggers '471* disclose

all the requirements of claim 12 that are equal or broader in scope to claim 1. (*See* Section VIII.A.3(a)(ii)). *Fox* discloses an elongated shaft and opposing jaw members movable from a first position to a second position. (Ex. 1006 at 2:62-3:2, 3:45-53, 4:33-38, 4:54-55, Figs. 3-5). *Wales* likewise discloses a shaft in the form of closure tube 20 with movable jaws 214 and 216 at the distal end thereof. (*See* Ex. 1008 at 3:50-55, Fig. 1, Fig. 5, 3:45-48, 3:61-4:3, Figs. 1-3). *Eggers '471* discloses a shaft (elongated barrel 15) that can have jaw-like members 18' and 19' at a distal end thereof. (Ex. 1009 at 6:19-25, 11:32-36, 11:47-54, 12:13-19, Figs. 7A-7B). At least the jaw members of *Fox* have the requisite length and the flat seal surfaces. (Ex. 1006 at Fig. 5, elements 11 and 117, 4:48-50). Energy is conducted to effect a tissue seal. (Ex. 1006 at 3:58, Abstract, 1:6-9, 2:62-65, 4:15-21, 3:50-53, 4:33-38, 4:47-50; Ex. 1001 at 3:7-10 (admitting *Fox* discloses sealing); Ex. 1008 at 1:52-54, 3:48-50; Ex. 1009 at 1:64-2:11, 4:47-51, 12:2-4).

With regard to the narrowing of claim 12 in the Shaft/Jaw Members Limitation as compared to claim 1, *Fox*, *Wales*, and *Eggers '471* each discloses a device with bilateral jaws, and thus that the jaw members are movable with respect to the elongated shaft under the broadest reasonable interpretation. (Ex. 1006 at Fig. 5, 4:54-55, Ex. 1008 at Figs. 7-9, (gaps between wireform 14/wireform 16 and tissue stop 18 when jaws are open in Figs. 7 and 8 are eliminated when jaws are closed (3:64-66) in Fig. 9); Ex. 1009 at Figs. 7A-7B, 10:31-44 (describing Figs.

5A-5B), 11:32-57 (likening Figs. 7A-7B to Figs. 5A-5B)).

(iii) Drive Rod Assembly Limitation

Claim 12 requires “a drive rod assembly that connects the jaw members to a source of electrical energy such that the first jaw member has a first electrical potential and the second jaw member has a second electrical potential.”

Under the broadest reasonable interpretation, the drive rod assembly (the component that imparts movement on the jaws) must be specifically designed to carry electrical energy of the first and second potentials to the jaw members. (Section VII.B). The drive rod 16 of *Eggers* ‘471 satisfies this limitation: “[d]rive rod 16 disposed in elongated barrel 15 has electrical terminals 17 that are connected to movable members 18 and 19 of working end 11 to provide an electrical potential therebetween.” (Ex. 1009 at 6:22-25, *see also* 6:68-7:9). Halves 16’ of drive rod 16 “have layer 45 of insulating material disposed on contacting surfaces 44, so that no current passes through those contacting surfaces.” (*Id.* at 7:49-51). *Eggers* ‘471 summarizes its electrical path as follows:

[T]he electrical circuit energizing each bipolar electrode extends from electrical terminals 17 on the proximal portion 30 of drive rod 16, through halve 16’ of drive rod 16 to proximal portion 31 of halve 16’. The outwardly disposed shank portion of the respective members 18 and 19 are in sliding electrical contact with the interior surfaces of indentations 42 of each of drive rod halves 16’, thereby providing a voltage potential across the tissue contacting portions of working end 11.

(*Id.* at 10:5-14). This confirms that halves 16' provide the first and second electrical potentials as required. (*Id.*, *see also* 6:22-25). *Fox, Eggers '142*, and *Wales* likewise disclose that their jaws have a first electrical potential and a second electrical potential, as required. (Section VIII.C.3(a)(ii); Ex. 1006 at 3:58, Abstract, 1:6-9, 2:62-65, 4:15-21, 3:50-53, 4:33-38, 4:47-50; Ex. 1008 at 1:52-54, 3:48-50; Ex. 1009 at 1:64-2:11, 4:47-51, 12:2-4; *see* Ex. 1001 at 3:7-10).

(iv) Handle Limitation

Claim 12 requires “a handle attached to the drive rod assembly for imparting movement of the first and second jaw members between the first and second positions.” *Eggers '471* discloses a handle attached to its drive rod assembly (*i.e.*, drive rod 16) made up of “handle members 12 and 13 joined for relative movement at pivot 14.” (Ex. 1009 at 6:20-21). The handle members include a disc 34 that captures a groove 33 of the drive rod, such that when the handles are moved the disc 34 moves drive rod 16 axially. (*Id.* at Fig. 2, 7:10-25, 7:31-45). Movement of the drive rod opens or closes the end effector members 18' and 19'. (*Id.* at 11:32-36, 11:47-54, 12:13-19, Figs. 7A-7B; *see also* 10:31-43, Figs. 5A-5B).

(v) Plurality Of Stop Members Limitation

Claim 12 requires “a plurality of non-conductive stop members” having the same requirements as in claim 1. For the reasons discussed with regard to claim 1, the combination of references supporting this Ground discloses this limitation.

(Section VIII.C.3(a)(iii); Ex. 1006 at Fig. 5, 4:25-29; Ex. 1007 at 6:23-25, 9:23-31, 9:33-36, 9:40-42, 14:25-29, 14:19-29, 14:43-52; Ex. 1004 at ¶ 37-38, 46-47).

(vi) Knife/Trigger Limitation

Claim 12 requires “a knife selectively movable to sever tissue along the tissue seal and a trigger which mechanically activates the knife for severing tissue proximate the tissue seal.” *Fox* discloses a knife and trigger for severing tissue along the tissue seal provided by its end effector. (Ex. 1006 at 5:17-19, Fig. 5, 6:60-63, 4:41). *Wales* discloses push bar 54 that pushes knife 42 when actuated by knife button 24. (Ex. 1008 at 4:4-9, 4:17-19, 4:23-30, 4:4:55-65).

(m) **Claim 13**

Claim 13 depends from claim 12 and requires that “the jaw members are configured to resist bending.” The ‘284 Patent discloses that for a jaw member to be configured to resist bending, it has a relatively thick proximal portion of the jaw member. (Ex. 1001 at 10:57-59). The Fig. 5 embodiment of *Fox*, in which the jaws have a three-dimensional configuration with a D-shaped cross-section, discloses that the jaw members are configured to resist bending. (Ex. 1006 at Fig. 5; *see also* 5:61-66 (cross section “improves the structural strength of the jaws and, as a result, the clamping force which may be applied to the jaws.”)). Likewise, the jaws of the end effector of *Wales* and at least the Figs. 7A and 7B embodiment of *Eggers* ‘471 have a two-dimensional cross section, and thus disclose the additional

limitation of this dependent claim. (Ex. 1008 at Figs. 1, 6-7, 8-9, 10:13-14, 6:17-19); Ex. 1009 at Figs. 7A-7B (jaw members taper distally), 11:64-12:2, 12:5-7).

(n) Claim 14

Claim 14 depends from claim 12 and requires that “the jaw members and the non-conductive stop members are configured such that the jaw members do not contact each other when the jaw members are moved to the second position.” *Fox* discloses this requirement by stating that an island of insulation “establish[es] an **insulative gap** between the conductive surfaces”, preventing the electrodes from touching. (Ex. 1006 at 4:25-29). *Eggers ‘142* also discloses such a gap. (Ex. 1007 at Figs. 8, 11, 12, Abstract 3:50-52 (“spacer arrangement serves to space the tissue grasping surfaces apart...when substantially in a closed orientation”)).

(o) Claim 15

Claim 15 depends from claim 12 and requires that “the jaw members and the non-conductive stop members are configured such that the distance between the jaw members when tissue is held therebetween is between about 0.002 inches and about 0.003 inches.” *Eggers ‘142* discloses values of T (the spacing between seal surfaces) as small 0.003 inches. (Ex. 1007 at 10:56-64). It further discloses that smaller distances, such 0.002 inches, can be employed although arcing may (but may not) occur. (*Id.* at 10:64-66; Ex. 1004 at ¶ 49-50).

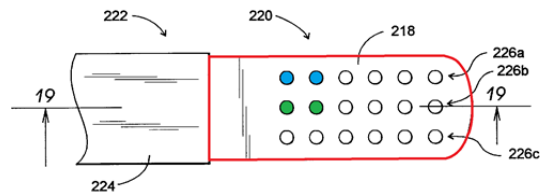
(p) Claim 16

Claim 16 depends from claim 12 and requires that “the non-conductive stop

members include a first pair of non-conductive stop members each being disposed a first distance from the inner facing surface of the jaw member and a second pair of non-conductive stop members each being disposed a second distance from the inner facing surface of the jaw member, and wherein the first distance is not equal to the second distance.” Petitioner submits that (a) this claim limitation lacks antecedent basis for the term “inner facing surface of the jaw member,” (b) this claim limitation is not supported by the disclosure of the ‘284 Patent and (c) assuming this limitation uses “distance” interchangeably with “height,” is at odds with the requirement of claim 12 (and PO’s arguments during prosecution) that “the non-conductive stop members [are] configured to maintain a uniform distance between the jaw members along the length thereof.” Stop members having a distance from an inner facing surface is nonsensical and at odds with similar claims of the parent ‘253 Patent, which recite distances from a periphery of jaw members. This claim violates 35 U.S.C. § 112 and thus is not amenable to construction.

Petitioner’s best guess is that this claim requires at least two pairs of stop members, where each pair has an intentionally different height from the surface of its respective jaw members. *Eggers ‘142* discloses this arrangement to a person of skill in the art, as it discloses that “spacing, T, represents the sum of the thickness’ T1 and T2 for the instant embodiment.” (*Id.* at 10:59-61, *see also* claim 10). A person of skill in the art, reading *Eggers ‘142*, would understand that T1 can be

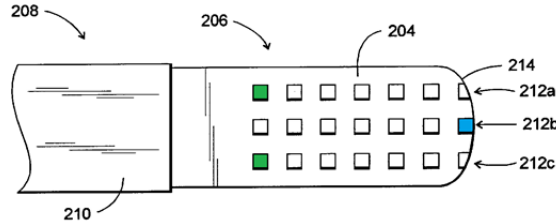
equal to T2 (and thus each height is 1/2 of the spacing “T”), or T1 and T2 can be different and nonetheless sum to total thickness T. (*See id.* at claim 10, Ex. 1004 at ¶¶ 51-53). Accordingly, incorporating the stop members of Figs. 8, 17, or 18 of *Eggers ‘142* into the end effector of Fig. 5 of *Fox* discloses this claim limitation when T1 and T2 are different for two different pairs of stop members. To the extent this claim requires two pairs of stop members having different distances from a periphery of a jaw member, the spacers of *Eggers ‘142* in green below have a different distance from the periphery (highlighted in red) than the spacers in blue:



(Ex. 1007 at Fig. 18). Thus, *Eggers ‘142* discloses the claimed arrangement.

(q) Claim 17

Claim 17 depends from claim 12 and requires that “the non-conductive stop members include at least one pair of non-conductive stop members arranged transversely atop at least one of the inner facing surfaces of one of the jaw members and a non-conductive stop member disposed at a distal tip of at least one of the jaw members.” Petitioner asserts that stop members are transversely atop a surface if they are across from one another with regard to the longer dimension of the sealing surface. Since this is a comprising claim, the green spacers below are a pair of non-conductive stop members arranged transversely atop the surface 218.



(Ex. 1007 at Fig. 17, 14:19-25; *see also* Fig. 18, 14:45-59). The blue spacer illustrates at least one non-conductive stop member disposed at the distal tip, the advantages of which are specifically discussed. (*See, e.g., Id.* at 9:50-58):

(r) Claim 18

Claim 18 depends from claim 12 and requires that “the distance between clamped jaw members is uniform along the length of the jaw members.” *Fox* and *Eggers ‘142* disclose a uniform gap. (Section VIII.A.3(a)(iii); Ex. 1006 at 4:25-29; Ex. 1007 at 10:54-11:8; Ex. 1004 at ¶¶ 38, 46-47).

D. Ground 4: Claim 11 Is Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Eggers ‘471, Wales, Fox, Eggers ‘142, and Slater*

1. Motivation to Combine

A person of ordinary skill in the art would have been motivated to use the manufacturing techniques of *Slater* to manufacture the end effector resulting from the combination of *Fox* and *Eggers ‘142* discussed in Ground 2. (Section VIII.B.2; Ex. 1004 at ¶¶ 91-98). Ground 3 explains why a person of ordinary skill in the art would have been motivated to combine *Eggers ‘471, Wales, Fox, and Eggers ‘142*. (Section VIII.C.2; Ex. 1004 at ¶ 111). Accordingly, a person of skill in the art would have combined *Eggers ‘471, Wales, Fox, Eggers ‘142, and Slater*.

2. Specific Identification of Challenge

(a) Claim 11

Ground 2 above explains *Slater's* manufacturing techniques combined with the manufacturing methods of *Eggers '142* and of islands of insulation in *Fox* discloses affixing non-conductive stop members to a jaw member using a molding process. (Ex. 1007 at 19:12-14, *see also* 11:25-35, 14:36-40; Ex. 1011 at Abstract, 2:37-40, 3:22-26, 5:34-39, 5:51-55, 5:62-65, 5:62-65, 7:22-32, 8:37-56; Ex. 1004 at ¶¶ 96-97). Accordingly, the combination renders dependent claim 11 obvious.

E. Ground 5: Claims 12-18 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over *Schulze* In View Of *Fox* and *Eggers '142*

1. Overview of the Prior Art

(a) *Schulze*

Schulze (Ex. 1012) issued on February 4, 1997, and is thus prior art under 35 U.S.C. § 102(b).⁶ It discloses “[a]n electrosurgical hemostatic instrument that provides a “bipolar endoscopic clamping, coagulation and cutting device.” (Ex. 1012 at Abstract). A “hollow sheath 12 comprised of an electrically insulative material extend[s] distally from the housing 11, a jaw closure tube 15 extend[s] through the sheath 12, and clamping jaw members 16, 17 extend[] from the distal end of closure tube 15.” (*Id.* at 3:15-19). Fig. 3 of *Schulze*, which is nearly identical to Fig. 5 of *Fox*, shows jaw members including flat seal surfaces that

⁶ Petitioner’s expert, David C. Yates, is a named inventor of *Schulze*.

“close towards each other...upon advancing the closure tube 15 over camming surfaces 16a, 17a of jaw members 16, 17, respectively.” (*Id.* at 3:20-24). “[G]enerator 35 provides electrosurgical energy to the electrodes 33, 34...energy is delivered through wires 37a, 37b which are coupled through housing 11, respectively, to contact 38 of the closure tube 15 and electrically insulated wire 39 extending through closure tube 15 to electrode 34. (*Id.* at 55-60; Ex. 1004 at ¶ 76). Energy is applied until “tissue is electrosurgically treated to a desired degree”; a knife is then advanced to cut engaged tissue. (*Id.* at 4:7-8).

2. Motivation to Combine

Ground 1 discusses why a person of skill in the art would have been motivated to incorporate the stop members of *Eggers* ‘142 into the end effector of *Fox* based on *Fox*’s discussion of an “island of insulation” to provide an “insulative gap.” (Section VIII.A.2; Ex. 1004 at ¶¶ 83-89). *Fox*’s Fig. 5 constitutes a motivation to look to the teachings of other references, like *Schulze*, that share an identical end effector design with respect to the features those references teach, as the identity of end effectors demonstrates that the teachings of such references will predictably operate with the *Fox* device. (Ex. 1004 at ¶¶ 74, 112-114). Moreover, since *Fox* focuses on the arrangement of its end effector, a person of skill in the art would have had a high expectation that the mechanical and electrical linkages between the handle and the end effector of *Schulze* (including its

knife drive mechanism) could have been incorporated into *Fox*. (Ex. 1004 at ¶¶ 32, 73, 115). This is particularly true since both devices rely on tube closure (Ex. 1006 at 4:39-41; Ex. 1012 at 3:19-24; Ex. 1004 at ¶¶ 31, 75) and provide identical slots in their end effectors to permit an identically shaped knife to reciprocate therein (Ex. 1006 at 5:17-24; Ex. 1012 at 3:24-45). When considering modifications to known bipolar endoscopic forceps like those of *Fox*, a person of skill in the art would have looked to other work by the same industry-leading company and inventors, particularly when the U.S. classifications overlap and the international classifications are identical. (Ex. 1004 at ¶¶ 72, 74, 114).

3. Specific Identification of Challenge

Fox, *Eggers '142*, and *Schulze* render claims 12-18 obvious under a claim interpretation where a drive rod assembly “connects the jaw members to a source of electrical energy” if it merely encloses conductors that carry electrical potential.

(a) Claim 12

(i) Preamble

Fox and *Schulze* disclose endoscopic bipolar forceps as required by the preamble. (Ex. 1006 at Abstract, 4:33-34; Ex. 1012 at 1:6-11, 1:24-35, 6:16-25)

(ii) Shaft/Jaw Members Limitations

Fox and *Schulze* each disclose the shaft and jaw members required by claim 12. (Ex. 1006 at 2:62-3:2, 3:45-53, 4:33-38, 4:54-55, Figs. 3-5; Ex. 1012 at 3:15-24 (shaft is hollow sheath 12), 3:65-67, Figs. 1, 3). The jaw members of Fig. 5 of

Fox and Fig. 3 of *Schulze* have the requisite length and the flat seal surfaces. (Ex. 1006 at Fig. 4, elements 416 and 417, Fig. 5, elements 11 and 117, 4:48-50; Ex. 1012 at 3:18-24, 3:46-50, Figs. 1, 3). Energy is conducted to effect a tissue seal. (Ex. 1006 at 3:58, Abstract, 1:6-9, 2:62-65, 4:15-21, 3:50-53, 4:33-38, 4:47-50; Ex. 1001 at 3:7-10; Ex. 1012 at Abstract, 1:6-11, 2:7-13, 4:7-8 (treating “to a desired degree” includes sealing)). *Fox* and *Schulze* disclose bilateral jaw movement. (Ex. 1006 at Fig. 5, 4:54-55; Ex. 1012 at Fig. 1, 3:19-24 (camming surfaces)).

(iii) Drive Rod Assembly Limitation

If this limitation is interpreted to merely require that the drive rod assembly (the component that imparts movement on the jaws) must only house or enclose conductors that actually carry electrical potential, *Schulze* discloses this limitation. Specifically, *Schulze* discloses that within its shaft (hollow sheath 12) is contained a jaw closure tube 15 (drive rod assembly) that “advance[s]...over camming surfaces 16a, 17a of jaw member 16, 17 respectively” to impart movement on the jaws. (Ex. 1012 at 3:15-24). Moreover, *Schulze* discloses that “[t]he energy is delivered through wires 37a, 37b which are coupled through housing 11, respectively, to contact 38 of the closure tube 15 and electrically insulated wire 39 extending through closure tube 15 to electrode 34.” (*Id.* at 3:56-60, Fig. 1; Ex. 1004 at ¶¶ 76-77). Accordingly, the closure tube 15 also “connects the jaw members to a source of electrical energy” under the interpretation addressed in this

Ground. Once connected, the claimed potentials are delivered to the jaws 16, 17. (*Id.* at 1:25-27, 3:46-51). *Fox* likewise discloses that the end effector members of their respective devices also have a first electrical potential and a second electrical potential, as required. (Section VIII.C.3(a)(ii); Ex. 1006 at 3:58, Abstract, 1:6-9, 2:62-65, 4:15-21, 3:50-53, 4:33-38, 4:47-50; *see* Ex. 1001 at 3:7-10).

(iv) Handle Limitation

Claim 12 requires “a handle attached to the drive rod assembly for imparting movement of the first and second jaw members between the first and second positions.” *Schulze* discloses the claimed handle attached to the closure tube 15 to impart movement as claimed. (Ex. 1012 at Fig. 1, 3:15-24, 3:65-4:4).

(v) Plurality Of Stop Members Limitation

Claim 12 requires “a plurality of non-conductive stop members” having the same requirements as in claim 1. For the reasons discussed with regard to claim 1, the combination of references supporting this Ground also discloses this limitation. (Section VIII.C.3(a)(iii); Ex. 1006 at Fig. 5, 4:25-29; Ex. 1007 at 6:23-25, 9:23-31, 9:33-36, 9:40-42, 14:25-29, 14:19-29, 14:43-52; Ex. 1004 at ¶¶ 37-38, 46-47).

(vi) Knife/Trigger Limitation

Fox discloses the required knife and trigger for severing tissue along the tissue seal provided by its end effector. (Ex. 1006 at 4:41, 5:17-19, Fig. 5, 6:60-63). *Schulze* discloses a knife (cutting element 22) and trigger (pusher knob 31). (Ex. 1012 at Fig. 1, Fig. 3, 3:24-40, 4:17-18).

(b) Claim 13

Fig. 5 of *Fox* (and the identical Fig. 3 of *Schulze*), in which the jaws have a three-dimensional configuration with a D-shaped cross-section, discloses the additional limitation of claim 13. (Ex. 1006 at Fig. 5; *see also* 5:61-66; Ex. 1012 at Fig. 1, 3; *see also* Figs. 2, 6-7, 9-13, 4:25-30; *compare* Ex. 1001 at 10:57-59).

(c) Claim 14

Claim 14 depends from claim 12 and is directed to the arrangement of non-conductive stop members on the jaw members. As discussed with regard to Ground 3, *Fox* and *Eggers '142* disclose the additional limitations of this dependent claim. (Section VIII.C.3(n); Ex. 1006 at 4:25-29; Ex. 1007 at Figs. 8, 11, 12, Abstract (spacing tissue-contacting surfaces), 3:50-52).

(d) Claim 15

Claim 15 depends from claim 12 and is directed to the arrangement of non-conductive stop members on the jaw members. As discussed with regard to Ground 3, *Eggers '142* discloses the additional limitations of this dependent claim. (Section VIII.C.3(o); Ex. 1007 at 10:56-64-66; Ex. 1004 at ¶ 49-50).

(e) Claim 16

Claim 16 depends from claim 12 and is directed to the arrangement of non-conductive stop members on the jaw members. As discussed in Ground 3, to the extent this dependent claim is supported by the '284 Patent, and under Petitioner's best guess as to the intended meaning of this claim, *Eggers '142* discloses this

arrangement. (Section VIII.C.3(p); Ex. 1007 at 10:56-61, claim 10, Figs. 8, 17, 18 (annotated as in Ground 3); Ex. 1004 at ¶¶ 51-53).

(f) Claim 17

Claim 17 depends from claim 12 and is directed to the arrangement of non-conductive stop members. As discussed in Ground 3, Fig. 18 of *Eggers '142* discloses the additional requirements of this dependent claim. (Section VIII.C.3(q); Ex. 1007 at Fig. 18, 14:45-59, 9:50-58).

(g) Claim 18

The limitation added in claim 18 appears in claim 1. As described above, combining *Fox* and *Eggers '142* discloses this limitation (Section VIII.A.3(a)(iii); Ex. 1006 at 4:25-29; Ex. 1007 at 10:54-11:8; Ex. 1004 at ¶¶ 38, 46-47).

IX. CONCLUSION

Petitioner requests institution of IPR of claims 1-18 of the '284 Patent based on the grounds presented above.

Respectfully submitted by

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