

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

ETHICON ENDO-SURGERY, INC. and  
ETHICON ENDO-SURGERY, LLC,

Plaintiffs,

v.

COVIDIEN LP, COVIDIEN SALES LLC, and  
COVIDIEN AG

Defendants.

Civil Action No.:

**COMPLAINT FOR  
DECLARATORY JUDGMENT**

Plaintiffs Ethicon Endo-Surgery, Inc. ("Ethicon") and Ethicon Endo-Surgery, LLC (collectively "Plaintiffs" or "EES") hereby file this Complaint for Declaratory Judgment against Covidien LP, Covidien Sales LLC, and Covidien AG ("Defendants" or "Covidien") and allege as follows:

**NATURE OF THE ACTION**

1. This complaint is an action for declaratory judgment of non-infringement of U.S. Patent Nos. 6,585,735 ("the '735 patent"), 7,118,587 ("the '587 patent"), 7,473,253 ("the '253 patent"), 8,070,748 ("the '748 patent"), and 8,241,284 ("the '284 patent") arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*

2. This action arises out of Covidien's refusal to acknowledge—as required under a 1999 Settlement Agreement between EES and Covidien's predecessor—that EES's new ENSEAL® X1 Large Jaw Tissue Sealer product ("ENSEAL X1"), a single-patient-use electro-surgical instrument for sealing and transecting vessels, does not infringe the '735, '587, '253, '748, and '284 patents.

**PARTIES**

3. Plaintiff Ethicon Endo-Surgery, Inc. is a corporation organized under the laws of the State of Ohio, having its headquarters and principal place of business at 4545 Creek Road, Cincinnati, OH 45242.

4. Plaintiff Ethicon Endo-Surgery, LLC is a corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 475 Street C, Los Frailes Industrial Park, Guaynabo, PR 00969.

5. Defendant Covidien LP is a limited partnership organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 15 Hampshire Street, Mansfield, MA 02048.

6. Defendant Covidien Sales LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 15 Hampshire Street, Mansfield, MA 02048.

7. Defendant Covidien AG is a corporation organized under the laws of Switzerland having its headquarters and principal place of business at Victor von Bruns-Strasse 19, Neuhausen am Rheinfall, CH-SH 8212, Switzerland.

8. On information and belief, the Defendants are all related entities within the corporate structure of Medtronic PLC.

**JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. On information and belief, this Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the benefits and protections of Massachusetts's

laws such that they should reasonably anticipated being subjected to the district court's jurisdiction. Defendants have also repeatedly consented to personal jurisdiction in this district. *See, e.g., Syntheon, LLC v. Covidien AG*, Case No. 1:16-CV-10244-ADB (D. Mass.).

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b). Defendants regularly conduct business in this judicial district and have consented to venue in this district in prior actions.

12. A real, immediate, substantial, and justiciable controversy exists between EES and Covidien with respect to the questions of infringement of the '735, '587, '253, '748, and '284 patents.

### **THE PATENTS-IN-SUIT**

13. Upon information and belief, Covidien AG is the owner by assignment of the '735, '587, '253, '748, and '284 patents, and Covidien LP and Covidien Sales LLC are licensed under the '735, '587, '253, '748, and '284 patents.

### **THE '735 PATENT**

14. The '735 patent, entitled "Endoscopic Bipolar Electrosurgical Forceps," issued on July 1, 2003 from U.S. Patent Application No. 09/621,029, which was filed July 21, 2000. The '735 patent states that it is a continuation of U.S. Patent Application No. 09/177,950, filed on October 23, 1998, now abandoned.

15. A true and correct copy of the '735 patent is attached hereto as Exhibit A.

### **THE '587 PATENT**

16. The '587 patent, entitled "Vessel Sealer and Divider," issued on October 10, 2006 from U.S. Patent Application No. 10/471,990, which was filed as application No. PCT/US01/11224 on April 6, 2001.

17. A true and correct copy of the '587 patent is attached hereto as Exhibit B.

**THE '253 PATENT**

18. The '253 patent, entitled "Vessel Sealer and Divider with Non-Conductive Stop Members," issued on January 6, 2009 from U.S. Patent Application No. 10/471,818, which was filed as application No. PCT/US01/11413 on April 6, 2001.

19. A true and correct copy of the '253 patent is attached hereto as Exhibit C.

**THE '748 PATENT**

20. The '748 patent, entitled "Vessel Sealer and Divider for Large Tissue Structures," issued on December 6, 2011 from U.S. Patent Application No. 12/833,270, which was filed July 9, 2010. The '748 patent states that it is a continuation of U.S. Patent Application No. 11/595,194, filed on November 9, 2006, now U.S. Patent No. 7,766,910.

21. A true and correct copy of the '748 patent is attached hereto as Exhibit D.

**THE '284 PATENT**

22. The '284 patent, entitled "Vessel Sealer and Divider with Non-Conductive Stop Members," issued on August 14, 2012 from U.S. Patent Application No. 12/348,748, which was filed January 5, 2009. The '284 patent states that it is a continuation of U.S. Patent Application No. 10/471,818, filed as application No. PCT/US01/11413 on April 6, 2011, now U.S. Patent No. 7,473,253.

23. A true and correct copy of the '284 patent is attached hereto as Exhibit E.

**BACKGROUND**

**A. THE PARTIES AND RELEVANT PRODUCTS**

24. EES and Covidien are direct competitors in the advanced energy surgical market.

25. The advanced energy surgical market is comprised generally of energy-based instruments that use bipolar energy or ultrasonic energy sources (or both).

26. EES and Covidien both market advanced bipolar energy and ultrasonic energy devices.

27. EES's advanced bipolar energy devices are marketed under the ENSEAL® brand.

28. EES developed ENSEAL X1 and has manufactured and used the product in the United States.

29. EES submitted a 510(k) premarket submission to the FDA concerning ENSEAL X1, and the FDA provided its premarket approval of the device on September 9, 2016. *See* Exhibit F (a true and correct copy of Ethicon's Press Release dated Sept. 12, 2016). EES is in the midst of preparing for a commercial launch of the product.

**B. FACTS RELATED TO DECLARATORY JUDGMENT JURISDICTION**

30. The parties and their predecessors are competitors in the medical device market, and have a long history of patent litigation between them.

31. In 1999, Ethicon and Covidien's predecessor entered into a Settlement Agreement, which disposed of several then-pending patent litigations ("1999 Settlement Agreement") (a true and correct copy of which is attached as Exhibit G). The 1999 Settlement Agreement is still effective and binding on Ethicon and Covidien.

32. The 1999 Settlement Agreement provides a mandatory pre-litigation mediation procedure for patent disputes between Ethicon and Covidien.

33. The mediation procedure requires the parties to submit to pre-litigation mediation in instances where: (1) one party believes that it has a claim anywhere in the world against another party that a product or process infringes a patent not within the scope of the immunity granted in the 1999 Settlement Agreement, or (2) one party wishes to resolve whether a new product or

process of such party not within the scope of the immunity granted under the 1999 Settlement Agreement infringes any patents of the other party.

34. Ethicon and Covidien have operated under the mediation procedure in connection with several prior patent litigations between them concerning other medical devices.

35. In 2004, for example, Covidien's predecessor (Tyco Healthcare Group LP) sued Ethicon for patent infringement in connection with certain energy-based, surgical devices. That case, captioned *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 3:04-CV-01702 (D. Conn.), was dismissed for lack of subject matter jurisdiction because the wrong party was named in the Complaint, and the Federal Circuit affirmed the dismissal. Covidien's predecessor again filed suit in 2010. In that case, captioned *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 3:10-CV-00060 (D. Conn.), Ethicon prevailed with the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") finding that Tyco's patent claims were invalid over the prior art. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968 (Fed. Cir. 2014).

36. In 2014, Covidien Sales LLC, Covidien LP f/k/a Tyco Healthcare Group, LP, and United States Surgical Corporation filed a patent infringement suit and sought a preliminary injunction against Ethicon's ACE+7 ultrasonic surgical device. In that case, captioned *Covidien Sales LLC v. Ethicon Endo-Surgery, Inc.*, No. 3:14-CV-00917 (D. Conn.), a preliminary injunction was granted against the ACE+7 device, and the district court declined to stay the injunction while Ethicon sought a stay pending appeal to the Federal Circuit. Within days after the district court denied Ethicon's motion to stay, the Federal Circuit stayed the injunction, and thereafter reversed entry of the same. The district court ultimately dismissed the case, but not before EES suffered significant financial and reputational damage.

37. In 2011, Ethicon learned that Covidien intended to introduce Sonicision, an ultrasonic device that would compete directly against Ethicon's ultrasonic products. Ethicon invoked the mediation process in the 1999 Settlement Agreement, identifying a number of patents that it believed Sonicision infringed. Covidien refused to mediate, contending that it had no obligation to do so until it was actually selling the Sonicision, even though it was making and using the device in preparation for its commercial launch. Ethicon noted that Covidien's approach undermined the purpose of the mediation process—to provide the parties with an opportunity to resolve patent disputes and, if not resolve them, to provide clarity as to each party's positions. Covidien continued to refuse to mediate, resulting in Ethicon filing a patent infringement action in December 2011. *See Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, No. 1:11-cv-871 (S.D. Ohio) (the "Ohio litigation").

38. Covidien moved to dismiss the Ohio litigation as premature because there had been no mediation and Sonicision was not yet on the market. That motion was withdrawn and the case was stayed while the parties engaged in a mediation. The mediation did not resolve Ethicon's claims, and the lawsuit continued. Shortly before the scheduled trial, the district court granted Covidien summary judgment of non-infringement and/or invalidity on each of the patents at issue. On appeal, the Federal Circuit reversed several aspects of the district court's rulings and remanded the case back to the district court. *See Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312 (Fed. Cir. 2015).

39. While that appeal was pending, Ethicon advised Covidien of additional patents that had issued that Ethicon believed the Sonicision product infringed. Ethicon invoked the mediation process outlined in the 1999 Settlement Agreement. At the close of one day of mediation (at which the parties agreed to continue discussions), Covidien filed a declaratory judgment action

against Ethicon seeking a declaration of no infringement and invalidity as to the patents Ethicon had identified in the mediation. *See Covidien Sales LLC v. Ethicon Endo-Surgery, Inc.*, No. 1:16-cv-00253-SJD (S.D. Ohio). That case has been consolidated into *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, No. 1:11-cv-871 (S.D. Ohio), and is currently pending.

40. On May 27, 2015, Ethicon filed a petition for *inter partes* review of the '284 patent with the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (hereinafter, "PTAB"), asserting that claims 1-18 of the patents are invalid as obvious under 35 U.S.C. § 103. Covidien opposed Ethicon's petition. On December 17, 2015, a divided panel of the PTAB issued a decision denying *inter partes* review based on a claim construction that neither Ethicon nor Covidien had urged. On April 25, 2016, Ethicon filed another petition challenging claims 1 and 3-11 of the '284 patent based on additional art that addressed this claim construction, but which had not been included in the first petition because the PTAB's claim construction was unforeseeable at the time. Covidien again opposed Ethicon's petition. On October 24, 2016, the PTAB issued a decision denying *inter partes* review in response to Ethicon's second petition.

41. In light of Covidien's previous patent litigation activities against Ethicon, including the harm suffered by Ethicon through the wrongly issued preliminary injunction, and in accordance with the mediation procedures of the 1999 Settlement Agreement, Ethicon sought confirmation from Covidien that its ENSEAL X1 device did not infringe any of Covidien's patents before Ethicon was in the midst of a commercial launch.

42. Thus, on or around May 19, 2016, Ethicon served Covidien with a notice of mediation (a true and correct copy of which attached hereto as Exhibit H) under the 1999 Settlement Agreement. The notice informed Covidien of Ethicon's determination that the ENSEAL X1 did



not infringe any Covidien patent. In the notice, Ethicon offered to provide samples of the ENSEAL X1 for Covidien's own evaluation.

43. On or around May 31, 2016, Covidien responded to Ethicon's mediation letter. In its response (a true and correct copy of which is attached as Exhibit I), Covidien declined Ethicon's offer to evaluate the ENSEAL X1 under the terms of the 1999 Settlement Agreement. Covidien asserted that it was not obligated to engage in the mediation process called for in the 1999 Settlement Agreement until Ethicon has begun commercial sales of the ENSEAL X1.

44. However, the 1999 Settlement Agreement does not require commercial sales of a new product prior to initiation of the mediation procedures. *See* 1999 Settlement Agreement (Ex. G), Sec. 7.1. Rather, it authorizes mediation regarding any new product.

45. On or around June 15, 2016, Ethicon responded by letter (a true and correct copy of which is attached hereto as Exhibit J) in which it informed Covidien that it was in breach of the mediation procedure under the 1999 Settlement Agreement and requested that Covidien reconsider its position. Ethicon also: (1) specifically noted that it had manufactured the ENSEAL X1 in the United States and would launch following FDA clearance and (2) specifically identified the '284 patent as not being infringed by the ENSEAL X1.

46. On or around June 26, 2016, Covidien responded by letter (a true and correct copy of which is attached hereto as Exhibit K) in which it declined to engage in mediation reciting the same argument that it was not obligated to mediate until there were commercial sales of the ENSEAL X1.

47. On or around August 8, 2016, Ethicon responded by letter (a true and correct copy of which is attached hereto as Exhibit L) in which it informed Covidien that there is no requirement in the 1999 Settlement Agreement that a product actually be marketed in order for a party to

initiate the mediation procedure, and that Ethicon's current activities, including the manufacture of the ENSEAL X1 in the United States, were sufficient to trigger the initiation of the mediation procedure. Ethicon also reiterated its readiness to provide samples of the ENSEAL X1 for Covidien's evaluation. In addition to the previously identified '284 patent, Ethicon specifically identified the '735, '587, '253, and '748 patents as not being infringed by the ENSEAL X1.

48. On or around August 31, 2016, Covidien responded by letter (a true and correct copy of which is attached hereto as Exhibit M) in which it again declined to engage in mediation.

49. On or around September 15, 2016, Ethicon responded by letter (a true and correct copy of which is attached hereto as Exhibit N) in which it stated its understanding of Covidien's position to be that the FDA's recent approval for sale of the ENSEAL X1 device (*see* Exhibit F) and Ethicon's past and on-going manufacture of the same does not trigger Covidien's obligations under the 1999 Settlement Agreement, and that only actual sale of an ENSEAL X1 device would trigger those obligations. Further, Ethicon requested that Covidien advise immediately if its position changed.

50. On or around September 26, 2016, Ethicon and Covidien met and conferred by telephone. During the call, Covidien did not agree to mediate with Ethicon, but asked if there were a mediation: (1) whether Ethicon would agree that the fact a mediation occurred is irrelevant to whether a "case or controversy" exists; (2) whether Ethicon is flexible in its request that Covidien evaluate the ENSEAL X1 during a 30-day period; and (3) whether there were any restrictions on whom at Covidien could evaluate the product. Ethicon agreed to respond shortly.

51. On or around September 29, 2016, Ethicon responded by letter (a true and correct copy of which is attached hereto as Exhibit O), stating that: (1) Ethicon cannot agree that the fact of a mediation occurring is irrelevant to whether a "case or controversy" exists; (2) given the passage

of four months since Ethicon had first invoked the mediation procedure provisions of the 1999 Settlement Agreement and the imminent launch of the ENSEAL X1, Ethicon cannot agree to further delays; and (3) Ethicon proposes that the parties follow the same rules utilized when Covidien provided Ethicon samples of the Sonicision in 2012 before its commercial launch, *i.e.*, Covidien agree that the samples are being provided solely for purposes of a mediation and any intellectual property review related to the mediation, and not for any commercial purpose. Ethicon also requested a prompt response setting forth Covidien's position.

52. On October 14, 2016, Covidien responded by letter (a true and correct copy of which is attached hereto as Exhibit P), finally agreeing to evaluate the ENSEAL X1 device and to mediate with Ethicon regarding whether the ENSEAL X1 infringes any of the Covidien patents identified by EES. Ethicon promptly provided Covidien samples of the ENSEAL X1 and technical drawings of the same, for the limited purpose of Covidien's infringement evaluation of the ENSEAL X1 with respect to the Covidien patents identified by EES for the mediation.

53. On December 6 and December 9, 2016, Covidien informed Ethicon that based on its evaluation of the ENSEAL X1 device and related information, it intended to raise the '735, '587, '253, '748, and '284 patents at the mediation, thereby making clear Covidien's position that, in its view, the ENSEAL X1 device infringes one or more claims of each of these patents.

54. On December 19, 2016, the parties engaged in a mediation, which did not result in a settlement or a covenant by Covidien not to sue on the '735, '587, '253, '748, or '284 patents.

55. Covidien's continued indication that the ENSEAL X1 infringes the '735, '587, '253, '748, and '284 patents, combined with Covidien's past assertions of patent infringement against Ethicon, are factors that create a real, immediate, substantial, and justiciable controversy between

EES and Covidien with respect to the question of infringement of the '735, '587, '253, '748, and '284 patents.

**COUNT I: DECLARATION OF NON-INFRINGEMENT OF THE '735 PATENT**

56. EES incorporates and realleges Paragraphs 1 through 55 above as if fully set out and stated herein.

57. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

58. There is a real, immediate, substantial, and justiciable controversy between EES and Defendants concerning whether the manufacture, use, sale, offer for sale, or importation into the United States of EES's ENSEAL X1 infringes any claim of the '735 patent.

59. The ENSEAL X1 has not infringed and does not directly or indirectly infringe any claim of the '735 patent.

60. The ENSEAL X1 does not satisfy at least the following limitations recited in claim 1 of the '735 patent: (1) "first and second jaw members pivotally attached in opposing relation relative to one another;" (2) "a drive rod assembly adapted for connecting said jaw members to a source of electrical energy such that said first jaw member has a first electrical potential and said second jaw member has a second electrical potential and said jaw members are capable of conducting bipolar energy through the tissue held therebetween;" (3) "a handle attached to said drive rod assembly for imparting movement of said first and second jaw members from said first and second positions;" and (4) "at least one stop member attached to at least one of said tissue sealing surfaces of one of said jaw members for controlling the distance between opposing sealing surfaces of said jaw members."

61. The ENSEAL X1 does not satisfy at least the following limitations recited in claim 9 of the '735 patent, the only other independent claim: (1) "first and second jaw members pivotally attached in opposing relation relative to one another;" (2) "a drive rod assembly adapted for connecting said jaw members to a source of electrical energy such that said first jaw member has a first electrical potential and said second jaw member has a second electrical potential and said jaw members are capable of conducting bipolar energy through the tissue held therebetween;" (3) "a handle attached to said drive rod assembly for imparting movement of said first and second jaw members from said first and second positions;" and (4) "at least one stop member attached to at least one of said tissue sealing surfaces of one of said jaw members for creating a gap distance of about 0.001 to about 0.006 inches between opposing tissue sealing surfaces of said jaw members."

62. EES seeks a judicial declaration that the ENSEAL X1 does not infringe, directly or indirectly, any claim of the '735 patent.

**COUNT II: DECLARATION OF NON-INFRINGEMENT OF THE '587 PATENT**

63. EES incorporates and realleges Paragraphs 1 through 62 above as if fully set out and stated herein.

64. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. There is a real, immediate, substantial, and justiciable controversy between EES and Defendants concerning whether the manufacture, use, sale, offer for sale, or importation into the United States of EES's ENSEAL X1 infringes any claim of the '587 patent.

66. The ENSEAL X1 has not infringed and does not directly or indirectly infringe any claim of the '587 patent.

67. The ENSEAL X1 does not satisfy at least the following limitations recited in claim 1 of the '587 patent: (1) "a drive rod assembly which imparts movement of the jaw members between the first and second positions," and (2) "a handle assembly attached to the housing which actuates the drive rod assembly, the handle assembly including a four-bar mechanical linkage designed to reciprocate the drive rod assembly to actuate the jaw members between the first and second positions, said four-bar mechanical linkage including two handles, a link and a rotating cam-like piston, the rotating cam-like piston, upon movement of the handles relative to one another, rotates to correspondingly translate the drive rod assembly to impart movement to the jaw members between the first and second positions."

68. The ENSEAL X1 does not satisfy at least the following limitations recited in claim 10 of the '587 patent, the only other independent claim: (1) "first and second jaw members pivotally attached to the shaft in opposing relation relative to one another"; (2) "a drive rod assembly which imparts movement of the jaw members between the first and second positions"; and (3) "a handle assembly attached to the housing which actuates the drive rod assembly, the handle assembly including a four-bar mechanical linkage designed to reciprocate the drive rod assembly to actuate the jaw members between the first and second positions, the handle assembly including two handles, a link and a rotating cam-like piston which cooperate with a spring to impart a uniform closure pressure against tissue grasped between the jaw members."

69. EES seeks a judicial declaration that the ENSEAL X1 does not infringe, directly or indirectly, any claim of the '587 patent.

**COUNT III: DECLARATION OF NON-INFRINGEMENT OF THE '253 PATENT**

70. EES incorporates and realleges Paragraphs 1 through 69 above as if fully set out and stated herein.

71. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

72. There is a real, immediate, substantial, and justiciable controversy between EES and Defendants concerning whether the manufacture, use, sale, offer for sale, or importation into the United States of EES's ENSEAL X1 infringes any claim of the '253 patent.

73. The ENSEAL X1 has not infringed and does not directly or indirectly infringe any claim of the '253 patent.

74. The ENSEAL X1 does not satisfy at least the following limitations recited in the claim 1 of the '253 patent: (1) "the jaw members being 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, the jaw members being independently movable with respect to the elongated shaft," and (2) "at least one non-conductive stop member disposed on an inner facing surface of at least one of the jaw members which controls the distance between the jaw members when tissue is held therebetween and wherein the distance between clamped jaw members is substantially uniform along the length of the jaw members."

75. The ENSEAL X1 does not satisfy at least the following limitations recited in the claim 6 of the '253 patent, the only other independent claim: (1) "at least one elongated shaft having opposing jaw members at a distal end thereof, the jaw members being independently movable with respect to the elongated shaft;" (2) "a drive rod assembly which 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 and the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal;" and (3) "at least one non-conductive and spaced-apart stop member disposed on an inner facing surface of at least one

of the jaw members which controls the distance between the jaw members when tissue is held therebetween and wherein the distance between clamped jaw members is substantially uniform along the length of the jaw members."

76. EES is seeks a judicial declaration that the ENSEAL X1 does not infringe, directly or indirectly, any claim of the '253 patent.

**COUNT IV: DECLARATION OF NON-INFRINGEMENT OF THE '748 PATENT**

77. EES incorporates and realleges Paragraphs 1 through 76 above as if fully set out and stated herein.

78. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

79. There is a real, immediate, substantial, and justiciable controversy between EES and Defendants concerning whether the manufacture, use, sale, offer for sale, or importation into the United States of EES's ENSEAL X1 infringes any claim of the '748 patent.

80. The ENSEAL X1 has not infringed and does not directly or indirectly infringe any claim of the '748 patent.

81. The ENSEAL X1 does not satisfy at least the following limitations recited in the claim 1 of the '748 patent: (1) "a movable handle being rotatable about a pivot pin operably disposed in the housing to force a drive flange of the drive assembly to move the jaw members between the first and second positions," and (2) "a finger actuator operatively coupled to the knife assembly, the finger actuator including two generally u-shaped flanges which rotate about a pivot to abut and force the cuff distally which, in turn, results in distal translation of the knife through an aperture defined in the pivot to cut tissue disposed between the jaw members."



82. The ENSEAL X1 does not satisfy at least the following limitations recited in the claim 8 of the '748 patent, the only other independent claim: (1) "a drive assembly disposed within the housing and configured to move the jaw members relative to one another about a pivot from a first position to a second position, the pivot defining an aperture therethrough," and (2) "a trigger assembly operatively coupled to the housing and operatively coupled to a knife assembly having a drive rod, wherein actuation of the trigger assembly selectively translates a knife of the knife assembly through the aperture defined in the pivot and tissue disposed between the jaw members."

83. EES seeks a judicial declaration that the ENSEAL X1 does not infringe, directly or indirectly, any claim of the '748 patent.

**COUNT V: DECLARATION OF NON-INFRINGEMENT OF THE '284 PATENT**

84. EES incorporates and realleges Paragraphs 1 through 83 above as if fully set out and stated herein.

85. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

86. There is a real, immediate, substantial, and justiciable controversy between EES and Defendants concerning whether the manufacture, use, sale, offer for sale, or importation into the United States of EES's ENSEAL X1 infringes any claim of the '284 patent.

87. The ENSEAL X1 has not infringed and does not directly or indirectly infringe any claim of the '284 patent.

88. The ENSEAL X1 does not satisfy at least the following limitation recited in the claim 1 of the '284 patent: "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, the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof."

89. The ENSEAL X1 does not satisfy at least the following limitation recited in the claim 12 of the '284 patent, the only other independent claim: (1) "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 and 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," and (2) "a plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of 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, the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof."

90. EES seeks a judicial declaration that the ENSEAL X1 does not infringe, directly or indirectly, any claim of the '284 patent.

**PRAYER FOR RELIEF**

**WHEREFORE**, EES respectfully requests that the Court enter judgment against

Defendants as follows:

- A. That EES's ENSEAL X1 has not infringed and is not infringing either directly, indirect, or otherwise any claim of the '735, '587, '253, '748, and '284 patents;
- B. That this case is "exceptional" within the meaning of 28 U.S.C. § 285 and an award to EES of reasonable attorney fees and expenses is appropriate;
- C. That EES is entitled to an award of costs; and
- D. Such other and further relief that this Court deems just and proper.

Dated: December 19, 2016

Respectfully submitted,

/s/ Jack I. Siegal

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