UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ETHICON ENDO-SURGERY, INC., et al.,	)	
Plaintiffs and Counterclaim-Defendants,	)	
v.	)	Civil No. 16-12556-LTS
COVIDIEN LP, et al.,	)	
Defendants and Counterclaim-Plaintiffs.	)	

FINDINGS OF FACT, RULINGS OF LAW, AND ORDER FOR JUDGMENT

April 24, 2020

SOROKIN, J.

Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (collectively, "Ethicon") sued Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, "Covidien") for a declaration that Ethicon's Enseal X1 Large Jaw vessel sealer does not infringe certain Covidien patents and that the patents are invalid. Doc. No. 1.[1] Covidien counterclaimed for infringement and asserted validity of the patents. Doc. No. 34.

The Court held a claim construction hearing, after which it issued an Order construing the disputed claim terms. Doc. No. 144. During the litigation, the parties stipulated to the dismissal of all but two patents: United States Patent Nos. 9,241,759 ("the '759 patent") and 8,323,310 ("the '310 patent"). Ethicon asserts non-infringement and invalidity as to all asserted claims of both remaining patents. Doc. No. 50; Doc. No. 264.

[1] Citations to "Doc. No. __" reference documents appearing on the court's electronic docketing system; pincites are to the page numbers in the ECF header.

The Court held a bench trial from September 23, 2019 to October 3, 2019, Doc. Nos. 234–241, resolved a motion to strike certain testimony presented at trial, Doc. No. 253, resumed trial on January 15 and January 16, 2020 to hear an expert witness who had been ill in the fall, Doc. Nos. 212, 258, 260, received post-trial filings in February, Doc. Nos. 262–270, and heard closing arguments in March, Doc. No. 272.

The Court now makes the following factual findings and rulings of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure.[2] The Court concludes that Ethicon has failed to establish invalidity and that Covidien has failed to establish infringement.

I. BACKGROUND

The patents at issue generally relate to features of advanced bipolar surgical instruments used to seal and cut tissue or blood vessels. Both Ethicon and Covidien produce and sell such instruments. The devices permit surgeons to grasp a vessel or tissue between two opposing jaws at the distal end of the instrument, apply energy to the vessel or tissue to form a seal—thereby stopping the blood flowing through it—and then cut the sealed tissue using a knife that moves along the length of the opposing jaws.

A. The ’759 Patent – the Asserted Claims

The ’759 patent is entitled “Vessel Sealer and Divider for Use with Small Trocars and Cannulas.” ’759 patent, cover. The Abstract describes “[a]n endoscopic bipolar forceps [that]

[2] The Court makes its findings based on the evidence admitted at trial and on the Court’s own observations of the sample devices the parties submitted to the Court for its examination.

To the extent that any findings of fact may be deemed conclusions of law, they shall also be considered conclusions of law; to the extent that any conclusions of law may be deemed findings of fact, they shall also be considered findings of fact. See Miller v. Fenton, 474 U.S. 104, 113-14 (1985).

includes a housing, a shaft affixed to the housing, and a pair of jaw members attached to a distal end of the shaft." Id.

Covidien asserts infringement of independent claim 1 and dependent claims 4, 6, 7, 10, and 11 of the '759 patent. The dependent claims all depend from claim 1, which recites:

> 1. An **endoscopic bipolar forceps**, comprising:
>
> a housing;
>
> a shaft defining a longitudinal axis, extending distally from the housing, and having a movable jaw member and a fixed jaw member at a distal end thereof, each of the movable and fixed jaw members adapted to connect to a source of electrosurgical energy such that the movable and fixed jaw members are capable of conducting energy through tissue grasped therebetween;
>
> a drive sleeve defining a proximal end and a distal end, the drive sleeve operably coupled to the movable jaw member at the distal end of the drive sleeve and configured to move the movable jaw member relative to the fixed jaw member from a first position wherein the movable jaw member is disposed in spaced relation relative to the fixed jaw member to a second position wherein the movable jaw member is closer to the fixed jaw member;
>
> a movable handle **of unitary construction** having a **finger loop** positioned towards a first end thereof, **a drive flange** positioned towards a second end thereof, and a locking flange disposed between the finger loop and the drive flange, the drive flange operably coupled to the drive sleeve towards the proximal end of the drive sleeve such that movement of the movable handle from an open position to a closed position moves the movable jaw member relative to the fixed jaw member from the first position to the second position;
>
> a selectively advanceable knife operable to cut the tissue grasped between the movable and fixed jaw members in a distal direction; and
>
> a selectively actuatable finger actuator operably coupled to the selectively advanceable knife,
>
> wherein, when the movable handle is disposed in the open position, the locking flange impedes actuation of the finger actuator and advancement of the selectively advanceable knife to cut the tissue grasped between the movable and fixed jaw members.

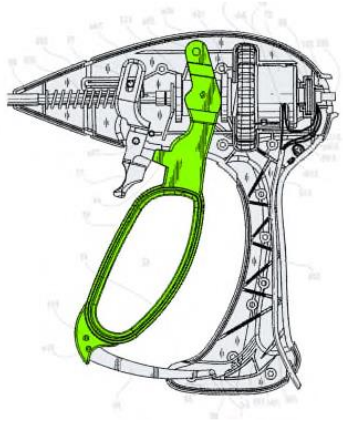
Id. at 23:5-41 (emphasis added).

The parties have stipulated that the accused Enseal X1 device practices all the limitations of the asserted claims except for those in bold text above. Doc. No. 255 ¶¶ 1-11. That is, they dispute whether the preamble of claim 1, which recites "[an] endoscopic bipolar forceps" is limiting and also whether the Enseal X1 practices the following three claim limitations: (1) a movable handle "of unitary construction" that includes (2) "a finger loop" and (3) "a drive flange" that is "operably coupled to the drive sleeve." Doc. Nos. 262, 264.

B. The '759 Patent – Findings of Fact

1. The Enseal X1 device and the "finger loop" limitation

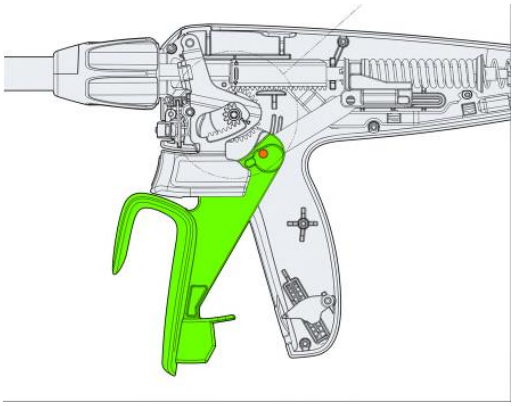
1. The "finger loop" described and claimed in the '759 patent and illustrated in Figure 30 below allows a user to open and close the jaws by inserting one or more of her fingers into the opening of the handle and pushing forward on the front (or distal) part of the handle to open the jaws, and pulling on the back (or proximal) part of the handle to close the jaws. Doc. No. 234 (9/23 Tr.) at 100:1-9.



'759 patent, Fig. 30 (annotated).

2. The Enseal X1 has a movable handle design called a "shepherd's hook." Doc. No. 237 (9/26 Tr.) at 114:21-115:2.

3. The shepherd's hook is not a closed curve. As the following figure illustrates, the shepherd's hook design is curved at the top and open on the distal side of the handle:



PTX-110 (Assembly Drawing of Enseal X1).[3]

4. The Enseal X1 shepherd's hook handle allows the user to pull back on the handle to move the jaws to a closed position and to push forward on the front part of the handle with one or more fingers—those that fit behind the front part of the handle—to move the jaws to an open position. Doc. No. 238 (9/27 Tr.) at 160:20-161:21.

5. Because it is a closed curve, a finger loop allows a user to employ more of her fingers than does a shepherd's hook to push the handle forward to open the jaws of the instrument. Unlike the shepherd's hook, which only allows the user to use the fingers that fit behind the front part of the handle structure, the finger loop allows a user to employ all the fingers that fit within the loop to push the handle forward. Doc. No. 238 (9/27 Tr.) at 91:10-17, 160:20-161:21; Doc. No. 260 (1/16 Tr.) at 22:12-23:6, 26:21-27:3; Doc. No. 237 (9/26 Tr.) at 153:15-25.

6. The finger loop handle is grasped by inserting one or more fingers into the opening of the closed loop.

[3] Citations to documents identified as "PTX-__, "DTX-__," and "JTX-__" are to copies of trial exhibits submitted to the Court by the parties. See Doc. No. 270 (Index of Admitted Trial Exhibits).

7. A finger loop receives a user's fingers and contains them in such a way as to prevent fingers from slipping off of the handle. Doc. No. 238 (9/27 Tr.) at 92:25-93:5; Doc. No. 260 (1/16 Tr.) at 28:23-29:24, 71:2-15. The user must pull her fingers out of the finger loop when extricating her hand from the handle

8. Surgeons hold devices like the Enseal X1 in all sorts of ways, including upside down. Doc. No. 237 (9/26 Tr.) at 116:7-10.

9. By virtue of being a closed loop, the finger loop handle contains the user's fingers when the handle is held in every direction—right side up or upside down, and backwards- or forwards-facing.

10. The shepherd's hook is grasped by holding on to the non-movable part of the handle and sliding one or more fingers against the front part of the handle—the hook—from below or the side.

11. The shepherd's hook handle does not hold the fingers in place. To remove her hand from the shepherd's hook handle, the user simply slips her fingers out of or away from the hook.

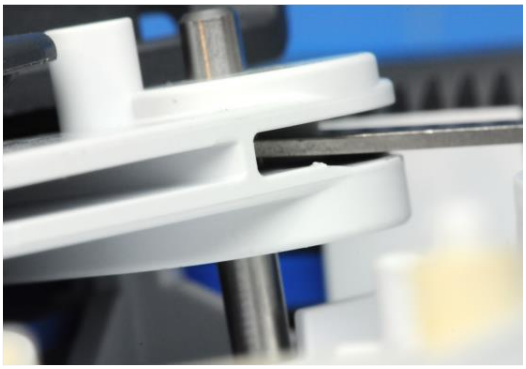
12. The shepherd's hook handle does not hold the user's fingers when the instrument is upside down because there is nothing to contain the fingers in place. The shepherd's hook handle does not even hold the user's fingers in place when the instrument is right side up. The fingers below the end of the end of the hook do not contact the hook part of the handle at all; those above the end of the hook are held in place by the user, not by the handle.

13. The finger loop allows the user to use all of her fingers in the loop to push the handle forward and to exert forward pressure with all her contained fingers—that is, if the user's fingers press or slide down on the front part of the handle, the closed loop will still contain them and facilitate continued forward pressure.

14. The shepherd's hook design allows only for some of the fingers—those fitting behind the hook—to push the handle forward. The user must hold those fingers in place. If the user's fingers slide down, the handle will not contain them and they will exert no forward pressure.

2. The Enseal X1 device and the "drive flange" limitation

15. The Enseal X1 includes added material in the form of raised structures projecting from each side of the movable handle as shown in the images below:



PTX-150 (Leinsing's Expert Report on Non-infringement), ¶ 196.

16. The raised structures were added to the movable handle in part to add strength at the location where force is being exerted on a pin that links the proximal end of the handle to the drive assembly. Doc. No. 237 (9/26 Tr.) at 120:17-122:19; Doc. No. 239 (10/1 Tr.) at 11:5-13:6, 30:1-14; Doc. No. 258 (1/15 Tr.) at 108:3-109:25.

17. The raised structures on the Enseal X1's movable handle are linked to the drive sleeve by means of a link pin which runs through the entirety of a pinhole positioned at the proximal end of the Enseal X1 movable handle where the raised structures are located. The pinhole runs through the moveable handle including through the raised structures on each side of the moveable handle. Doc. No. 237 (9/26 Tr.) at 117:10-118:15, 120:17-121:17; Doc. No. 239 (10/1 Tr.) at 11:5-22.

18. When the user applies force to the Enseal X1 movable handle, force is transmitted to the link component through the link pin. Doc. No. 237 (9/26 Tr.) at 119:5-14.

19. The link pin connects the proximal portion of the movable handle to a link that couples the handle to a "slider," which causes the drive sleeve to move back-and-forth (or reciprocate) when the movable handle is operated. Doc. No. 237 (9/26 Tr.) at 119:5-14; Doc. No. 238 (9/27 Tr.) at 167:6-168:2; Doc. No. 258 (1/15 Tr.) at 123:8-125:25.

20. The annulus (or inside cylinder) of the pinhole located in the moveable handle (including the part of the handle where the raised structures are located) exerts force on the link pin. The entire annulus of the pinhole exerts force on the link pin. Doc. No. 237 (9/26 Tr.) at 117:10-121:17; Doc. No. 258 (1/15 Tr.) at 97:3-98:12.

21. Ethicon's expert witness, Mr. Karl Leinsing, created a modified Enseal X1 device (PTX-502) from which the raised structures on the movable handle were removed with a diamond saw. Doc. No. 238 (9/27 Tr.) at 98:24-99:23.[4]

22. The jaws of this modified device could still open and close in an apparently normal manner after the raised structures were removed from the handle. Doc. No. 238 (9/27 Tr.) at 101:21-102:24; Doc. No. 260 (1/16 Tr.) at 38:19-23, 39:20-41:5.

23. If the drive flanges 47a and 47b on the patented instrument were removed, the instrument would not function because no force would be transmitted from the movable handle to the drive sleeve. Doc. No. 238 (9/27 Tr.) at 110:24-111:15; Doc. No. 260 (1/16 Tr.) 37:6-18.

[4] Before trial, Covidien moved to exclude evidence regarding the modified Enseal X1 device because it was produced after the close of fact and expert discovery. Doc. No. 198. Ethicon opposed. Doc. No. 200. After reviewing the parties' submissions and hearing argument on the motion, the Court denied the motion without prejudice for the reasons stated in open court. Doc. No. 227 at 10-12. Covidien did not renew its motion at trial or in its post-trial submissions. In any event, the Court has determined that Covidien was not prejudiced by the late production of this evidence.

3. U.S. Patent No. 6,419,675 ("Gallo")[5]

24. Modifying Gallo's four pliable jaw members and tubular sheath mechanism to arrive at the movable/fixed jaw members and drive sleeve configuration of the '759 patent would have required a substantial re-design of the Gallo device. Doc. No. 258 (1/15 Tr.) at 138:4-142:15.

25. Gallo does not disclose a locking flange on the movable handle. Doc. No. 258 (1/15 Tr.) at 144:17-148:4. The feature that Ethicon's expert witness, Mr. Leinsing, identified as the locking flange on Gallo's movable handle—drive head (92)—is the same component he identified as the drive flange. PTX-088, Fig. 4 (element 92); Doc. No. 239 (10/1 Tr.) at 58:10-17; Doc. No. 258 (1/15 Tr.) at 144:23-151:9.

26. Mr. Leinsing did not consider the amount of time or resources it would have taken to modify Gallo to produce the '759 patent device. Doc. No. 239 (10/1 Tr.) at 59:8-60:6.

27. Modifying the device disclosed in Gallo to arrive at the '759 patent device would have required an extensive re-design of the Gallo device, including re-designing at least the jaw members, shaft and shaft assembly, the mechanism used to close the jaw members, and the movable handle. Doc. No. 258 (1/15 Tr.) at 137:25-151:20.

28. A person of ordinary skill in the art at the time of the '759 patent would not have been motivated to combine the teachings of Gallo with the other prior art references on which Ethicon relies to arrive at the '759 patent's complete invention with any reasonable expectation of success. Doc. No. 258 (1/15 Tr.) at 138:4-139:7, 141:24-142:15, 143:24-144:16, 148:5-149:3, 156:18-159:3; Doc. No. 260 (1/16 Tr.) at 8:21-10:20.

[5] U.S. Patent No. 6,419,675 ("Gallo") (PTX-088) issued on July 16, 2002; there is no dispute that it is prior art to the '759 patent under pre-AIA 35 U.S.C. § 102(a).

C. The ’310 Patent – the Asserted claims

Entitled “Vessel Sealing Jaw with Offset Sealing Surface,” the ’310 patent is directed to “forceps for sealing and/or cutting tissue.” ’310 patent, cover; id. at 1:7-8. The specification teaches that the jaw members are designed to permit the grasping and cutting of tissue between the sealing surfaces. Id. at 1:56-61 (“The end effector assembly includes a pair of jaw members disposed in opposing relation relative to one another. Each jaw member has an opposing sealing surface and one or both of the jaw members is moveable relative to the other about a pivot from a first position to a second position for grasping tissue therebetween.”); id. at 3:34-39 (“Moveable handle 40 of handle assembly 30 (see FIG. 1) is ultimately connected to a drive assembly 150 (see FIG. 5) that, together, mechanically cooperate to impart movement of jaw members 110 and 120 from an open position to a clamped position to grasp tissue between sealing surfaces 112 and 122.”); id. at 3:43-48 (“When jaw members 110 and 120 are disposed in the clamped position, the knife channel halves together form a complete knife channel 115 (see FIG.3B), such that a blade 185 of a knife assembly 140 (see FIG. 4) can translate distally therethrough cutting tissue grasped between the jaw members 110 and 120.”).

The specification also teaches that “[w]hen the jaw members are disposed in the second position, a plane is formed between the opposing sealing surfaces of each of the jaw members,” id. at 1:63-65, and that the sealing surface of the lower jaw member lies below the longitudinal axis, id. at 4:6-8. “As a result of sealing surface 122 being positioned below the longitudinal axis ‘A’ when moveable jaw member 110 is moved into the clamped position to grasp tissue therebetween, the plane created between sealing surfaces 112 and 122 lies below longitudinal axis ‘A.’” Id. at 4:15-20. The specification teaches that the offset configuration claimed by the ’310

patent improves the mechanical advantage and uniform pressure distribution across the jaw members to enable better tissue sealing. Id. at 3:55-58, 4:42-45, 4:52-54.

Covidien asserts infringement of independent claims 1 and 16, and dependent claims 4, 7, 8, and 19. Claims 4, 7, and 8 depend from claim 1, which recites:

> 1. A forceps, comprising:
>
> a shaft having a longitudinal axis defined therethrough and an end effector assembly disposed at a distal end thereof, the end effector assembly including:
>
> a pair of jaw members disposed in opposing relation relative to one another, each jaw member having an opposing sealing surface, at least one jaw member pivotable relative to the other about a pivot pin from a first position to a second position for grasping tissue therebetween;
>
> wherein the pivot pin is offset in a first direction from the longitudinal axis; and
>
> wherein, when the jaw members are disposed in the second position, **a plane is formed between the opposing sealing surfaces**, the plane offset in a second, opposite direction from the longitudinal axis.

'310 patent at 6:9-24 (emphasis added).[6] The only issue as to both infringement and invalidity is whether the Enseal X1 practices the "plane" limitation in bold text. Doc. No. 267 ¶ 210.

D. The '310 Patent – Findings of Fact

1. The construction of "plane"

29. A person of ordinary skill in the art at the time of the invention would have understood that the claimed plane is the mid-plane between the sealing surfaces when the jaw members are in the closed position, even if that position leaves a gap between the sealing surfaces. Doc. No. 235 (9/24 Tr.) at 62:2-25.

[6] The "plane" limitation in independent claim 16 is substantially similar to that in claim 1; it recites "a plane is formed between the opposed sealing surfaces." '310 patent (claim 16). The parties agree that the "plane" term has the same meaning in both independent claims. Doc. No. 267 ¶ 190.

30. A person of ordinary skill in the art at the time of the '310 patent invention would have understood that an advanced bipolar instrument must provide a way to maintain a gap between opposing sealing surfaces to prevent contact between them. Doc. No. 234 (9/23 Tr.) at 76:8-23; Doc. No. 235 (9/24 Tr.) at 24:1-25:12, 38:11-39:25, 125:18-126:9, 231:18-232:4.

31. A person of ordinary skill in the art at the time of the '310 patent invention would have understood that when the opposing sealing surfaces of an advanced bipolar instrument come into direct contact during use, the instrument will short-circuit and not function properly. Doc. No. 235 (9/24 Tr.) at 24:1-25:12, 38:11-39:25, 125:18-126:9, 231:18-232:4; see also Doc. No. 234 (9/23 Tr.) at 76:8-23.

32. A person of ordinary skill in the art at the time of the invention would have understood that the dots in Figures 1 and 2 of the '310 patent represent stop members, which function to prevent the opposing sealing surfaces from touching each other when the jaw members are in the closed position because such touching would short-circuit the device and make it stop working. Doc. No. 235 (9/24 Tr.) at 39:17-25, 59:10-16, 232:9-233:7; '310 patent, Fig. 2 (showing six insulating dots).

2. The Enseal X1 device and the "plane" limitation

33. Mr. Gregory Trees was the principal design engineer for the Enseal X1 project. Doc. No. 237 (9/26 Tr.) at 64:13-23.

34. In connection with his infringement analysis for the '310 patent, Covidien's expert witness, Dr. William Durfee, reviewed and analyzed a CAD Assembly File produced by Ethicon in this litigation. Doc. No. 235 (9/24 Tr.) at 134:17-136:5.

35. Mr. Trees provided Dr. Durfee with the Enseal X1 CAD Assembly File—which Ethicon and its employees maintain and rely on in the ordinary course of Ethicon's business—that Dr. Durfee reviewed and analyzed. Doc. No. 237 (9/26 Tr.) at 127:18-128:24.

36. Based on the CAD Assembly File, Dr. Durfee calculated that the mid-plane between the sealing surfaces of the opposing jaw members when they are in the closed position is 0.00145 inches below the longitudinal axis of the shaft. Doc. No. 235 (9/24 Tr.) at 160:5-9.

37. The distance of .00145 inches is approximately a third the thickness of a piece of paper. Doc. No. 235 (9/24 Tr.) at 228:5-13.

38. CAD Assembly Files may be suitable for certain types of measurements—such as the location of the longitudinal axis of a shaft whose width is stable along its length—but is not reliable for mapping the precise spatial relationships of components of a device whose dimensions are not stable. See, e.g., Doc. No. 237 (9/26 Tr.) at 91:11-94:4. It is not a reliable basis for determining precise distances between components of manufactured devices. Id.

39. Actual physical devices have manufacturing tolerances associated with the dimensions of each component. Doc. No. 235 (9/24 Tr.) at 216:5-217:9.

40. Manufacturing tolerances for an instrument such as the Enseal X1 can be between .001 to .005 inches. Id. at 216:11-16.

41. Applying manufacturing tolerances to Dr. Durfee's measurements means that the offset he calculated based on the CAD Assembly File of the Enseal X1 could be zero or even less than zero on actual physical Enseal X1 devices. Doc. No. 235 (9/24 Tr.) at 217:10-24.

42. On the Enseal X1, there is a distal pin on the lower jaw member to set the gap between the opposing sealing surfaces of the jaw members. Doc. No. 235 (9/24 Tr.) at 176:11-19.

43. In the CAD Assembly File on which Dr. Durfee relied, the top of the distal pin extends above the upper sealing surface by 0.0014 inches. Doc. No. 238 (9/27 Tr.) at 33:15-34:16.

44. In an actual Enseal X1 device, the top of the distal pin does not extend above the upper sealing surface, but instead rests right on that upper sealing surface. Doc. No. 235 (9/24 Tr.) at 180:17-181:5.

45. Dr. Durfee also took photographs of four Enseal X1 devices to determine the location of the longitudinal axis of the shaft. Doc. No. 235 (9/24 Tr.) at 163:2-163:8; DTX-130.

46. Dr. Durfee did not take any measurements of the four physical devices directly. Doc. No. 235 (9/24 Tr.) at 219:10-221:1.

47. For each of the four Enseal X1 devices, Dr. Durfee closed the jaws of the device, oriented it axially so that a camera was looking directly at the jaws, and then took a picture of the device. Doc. No. 235 (9/24 Tr.) at 164:8-21.

48. After taking photographs of each device, Dr. Durfee placed the images into an image software program to locate the longitudinal axis on each of the photographs of the four Enseal X1 devices, and then drew a red line representing what he identified to be the longitudinal axis on each photograph. Doc. No. 235 (9/24 Tr.) at 163:9-165:17; DTX-130.

49. To locate the longitudinal axis on the photographic images of the Enseal X1 devices, Dr. Durfee used only a single reference point along the shaft; he did not use points along the length of the shaft to locate the longitudinal line. Doc. No. 235 (9/24 Tr.) at 222:16-223:12.

50. The gap between the sealing surfaces of the jaw members of the Enseal X1 device when they are in the closed position is .008 inches. Doc. No. 235 (9/24 Tr.) at 147:16-18. Therefore, the mid-plane is located .004 inches from the top sealing surface and .004 inches from the bottom sealing surface.

51. Neither Dr. Durfee nor Covidien presented any evidence that the use of photographs to measure small distances between components of physical devices, such as the distances at issue in the plane limitation, is a standard or generally-accepted method of measuring such distances.

52. Neither Dr. Durfee nor Covidien presented any evidence regarding the error rate introduced either by (a) the use of photographs to measure the spatial relationships at issue, or (b) the positioning of the devices (and of the camera) before the photographs are taken, to ensure that parallel lines (here, the longitudinal axis and the mid-plane) may be accurately identified. There is an error rate related to each of these processes, as there is with any measurement methodology.

53. Given the absence of any evidence regarding the error rates associated either with the use of photographs to measure spatial relationships among components of physical devices or with the positioning of the devices and the camera for purposes of ensuring the accurate identification of parallel lines, and the absence of any evidence that using photographs to measure the kind of spatial relationships at issue here is a standard or generally accepted approach, Covidien has failed to establish that the use of photographs is a reliable methodology.

3. U.S. Patent Application Publication No. 2003/0229344 ("Dycus '344")[7]

54. A person of ordinary skill in the art looking at figures 39C and 39D of Dycus '344 would not expect the shaft (3012) to move vertically with respect to the outer sleeve (3130) when the jaw members go from an open to a closed position, and thus would not expect that the distance between the top of the shaft (3012) and the top of the outer sleeve (3130) in Figure 39D to be greater than that same distance in Figure 39C. Doc. No. 241 (10/3 Tr.) at 9:2-10:24.

[7] U.S. Patent Application Publication No. 2003/0229344 ("Dycus '344") (PTX-076) was published in 2003; there is no dispute that it is pre-AIA prior art to the '310 patent.

55. A person of ordinary skill in the art would understand that because the shaft (3012) in Figures 39C and 39D of Dycus '344 is shown at different locations with respect to outer sleeve (3130), those figures were not drawn accurately to reflect the precise dimensions and spatial relationships of the components of the device they illustrate. Doc. No. 241 (10/3 Tr.) at 9:2-10:24.

56. A person of ordinary skill in the art would not expect the knife blade (3190) to move vertically with respect to the outer sleeve (3130) when the jaw members go from an open to a closed position, and thus would not expect the knife blade (3190) to be located in different places in the outer sleeve (3130) in Figures 39C and 39D. Doc. No. 234 (9/23 Tr.) at 106:15-107:2; Doc. No. 241 (10/3 Tr.) at 12:16-14:2.

57. A person of ordinary skill in the art would understand that because the knife blade (3190) is shown in different places with respect to outer sleeve (3130) in Figures 39C and 39D of Dycus '344, those figures were not drawn accurately to reflect the precise dimensions and spatial relationships of the components of the device they illustrate. Doc. No. 234 (9/23 Tr.) at 106:15-107:2; Doc. No. 241 (10/3 Tr.) at 12:16-14:2.

58. A person of ordinary skill in the art would not expect the knife slot (3170) to move with respect to the pivot pin (3160) when the jaw members go from an open to a closed position, and thus would not expect the knife slot (3170) to be shown in different positions with respect to the pivot pin (3160) in Figures 39C and 39D. Doc. No. 234 (9/23 Tr.) at 106:6-14; Doc. No. 241 (10/3 Tr.) at 11:3-12:15.

59. A person of ordinary skill in the art would understand that because the knife slot (3170) is shown in different positions with respect to the pivot pin (3160) in Figures 39C and 39D of Dycus '344—in the former, it is shown as passing through the pivot pin and in the latter it is shown as being below the pivot pin and not as passing through it—those figures were not drawn

accurately to reflect the precise dimensions and spatial relationships of the components of the device they illustrate. Doc. No. 234 (9/23 Tr.) at 106:6-14; Doc. No. 241 (10/3 Tr.) at 11:3-12:15.

60. A person of ordinary skill in the art would not expect the knife blade (3190) to be taller than the knife slot (3170), as the knife blade would not be able to slide through the knife slot, and would thus understand that because the knife blade (3190) is taller than the knife slot (3170) in Figures 39C and 39D, the figures were not drawn accurately to reflect the precise dimensions and spatial relationships of their components. Doc. No. 241 (10/3 Tr.) at 14:3-16:9.

4. U.S. Patent No. 6,056,735 ("Okada")[8]

61. A person of ordinary skill in the art would not expect the same component to be different sizes when illustrated as being in the open and closed positions in the same figure. Doc. No. 241 (10/3 Tr.) at 27:20-29:12.

62. A person of ordinary skill in the art would understand that because the same holding member (306) is shown as being different sizes when in the open and closed positions in Figure 54 of Okada, that figure was not drawn accurately to reflect the precise dimensions and spatial relationships of the components of the device it illustrates. Doc. No. 241 (10/3 Tr.) at 27:10-29:12.

63. A person of ordinary skill in the art would understand that the inventors of the device claimed in Okada were not concerned with where the jaws of the device came together in relation to the longitudinal axis of the shaft because the figures across Okada show different spatial relationships between these features. Doc. No. 241 (10/3 Tr.) at 29:13-31:8.

[8] U.S. Patent No. 6,056,735 ("Okada") (PTX-087) issued on May 2, 2000; there is no dispute that it is pre-AIA prior art to the '310 patent.

5. WO2008/040485 ("Geiselhart")[9]

64. With respect to Figure 18 of Geiselhart, a person of ordinary skill in the art would understand that the rotation axis 1 would be located on the plane where the mouth parts 10 and 10' come together, Doc. No. 241 (10/3 Tr.) at 39:11-42:10, because the specification discloses that "[t]he rotation axis 1 here lies substantially on the longitudinal axis of the mouth parts 10, 10'." PTX-101 at 12.

65. A person of ordinary skill in the art would understand that Figure 18 was not drawn accurately to reflect the precise dimensions and spatial relationships of the components of the device illustrated in that figure because the location of the rotation axis 1 with respect to where the two mouth parts 10 and 10' come together conflicts with the written specification regarding the same relative locations. PTX-101 at 12 ("The rotation axis 1 here lies substantially on the longitudinal axis of the mouth parts 10, 10'."); Doc. No. 241 (10/3 Tr.) at 39:11-42:10.

II. LEGAL STANDARD

"The patentee has the burden of proving infringement by a preponderance of the evidence." Amgen Inc. v. Sandoz Inc., 923 F.3d 1023, 1027 (Fed. Cir. 2019). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." Duncan Parking Techs., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1360 (Fed. Cir. 2019) (internal quotation marks and citation omitted). "[A] product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

[9] WO2008/040485 ("Geiselhart") (PTX-101) was published on April 10, 2008; there is no dispute that it is pre-AIA prior art to the '310 patent.

If an independent claim is not infringed, there can be no infringement of any dependent claims that depend from that claim. Taurus IP, LLC v. DaimlerChrysler Corp., 726 F.3d 1306, 1325, n.11 (Fed. Cir. 2013) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed . . . .") (quoting Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989)).

"A patent shall be presumed valid," and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C § 282(a); Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. 91, 95 (2011) (invalidity defenses must be proved by "clear and convincing evidence"). "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282(a).

III. RULINGS OF LAW

A. '759 Patent – Infringement

The parties dispute whether the preamble of claim 1, which recites "[an] endoscopic bipolar forceps" is limiting and, if it is not, whether the Enseal X1 nevertheless infringes by practicing three claim limitations pertaining to the claimed "movable handle": (a) it has a finger loop, (b) it has a drive flange, and (c) it is "of unitary construction."

1. The preamble

"Whether a preamble limits a claim is a question of claim construction." Howmedica Osteonics Corp. v. Zimmer, Inc., 640 F. App'x 951, 955 (Fed. Cir. 2016) (citing Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002)). "Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[ ] . . . patent to

gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" Catalina, 289 F.3d at 808 (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)). "While there is no simple test for determining when a preamble limits claim scope, [the Federal Circuit has] set forth some general principles to guide that inquiry." Am. Med. Sys. v. Biolitec, Inc., 618 F.3d 1354, 1358 (Fed. Cir. 2010).

"Generally, the preamble does not limit the claims." Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1346 (Fed. Cir. 2002). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett–Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (intneral quotation marks and citation omitted). But a preamble does not limit an invention "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997). "[A] preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Catalina, 289 F.3d at 809.

Here, the term "endoscopic bipolar forceps" is recited only in the preambles of asserted '759 patent claims; it does not appear in the body of any claim. See '759 patent at 23:5-41, 23:48-24:4; 24:8-14, 24:23-30. Reading the claim body on its own, it is apparent that the preamble at issue merely describes a purpose or intended use for the invention, and that the claim body describes a structurally complete invention.

The patent specification confirms this reading of the preamble. It states that "[t]he present disclosure relates to an electrosurgical forceps and more particularly, . . . to an endoscopic bipolar

electrosurgical forceps for sealing and/or cutting tissue." Id. at 1:19-22. The specification explains that endoscopic surgical instruments are used "[a]s an alternative to open forceps for use with open surgical procedures, . . . for remotely accessing organs through smaller, puncture-like incisions," and that "[a]s a direct result thereof, patients tend to benefit from less scarring and reduced healing time." Id. at 1:29-34. It then goes on to discuss some of the requirements and attributes of endoscopic instruments. Id. at 1:35-36 ("Endoscopic instruments are inserted into the patient through a cannula, or port, which has been made with a trocar."); id. at 1:37-42 ("Typical sizes for cannulas range from three millimeters to twelve millimeters. Smaller cannulas are usually preferred, which, as can be appreciated, ultimately presents a design challenge to instrument manufacturers who must find ways to make endoscopic instruments that fit through the smaller cannulas."); id. at 3:41-43 ("It would be desirous to develop a smaller, simpler endoscopic vessel sealing instrument which can be utilized with a 5 mm cannula."). And the Summary states that "[t]he present disclosure relates to an endoscopic bipolar forceps which is designed to be utilized with a 5 mm trocar or cannula and includes a housing and a shaft affixed to the distal end of the housing." Id. at 3:52-55.

That said, the specification does not limit the invention to instruments used endoscopically. Rather, it discloses that:

> Although the majority of the figure drawings depict a bipolar forceps 10 for use in connection with endoscopic surgical procedures, the present disclosure may be used for more traditional open surgical procedures. For the purposes herein, the forceps 10 is described in terms of an endoscopic instrument, however, it is contemplated that an open version of the forceps may also include the same or similar operating components and features as described below.

'759 patent at 6:54-62.

In light of these disclosures and the Court's determination that the claim body describes a structurally complete invention, the Court concludes that the preamble at issue in the asserted

claims of the '759 patent is only "meant to describe the principal intended use of the invention but not to import a structural limitation or to exclude from the reach of the claims an assembly that does not include [the use contemplated by the preamble]." Georgetown Rail Equip. Co. v. Holland, 867 F.3d 1229, 1236-37 (Fed. Cir. 2017). Here, as in Catalina, "deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the [invention] itself." 289 F.3d at 810. The deletion of the preamble from the claims of the '759 patent, or its substitution with a generic term like "apparatus" or "device," does not affect the structure of the claimed invention because the term "endoscopic" does not provide any additional structure to the apparatus claims of the '759 patent. Nor do the asserted claims recite or suggest an overall size limitation on the patented device—e.g., that it be small or narrow enough to be used only in endoscopic procedures.

The Court therefore concludes that the preamble at issue is not limiting.[10]

2. The "finger loop" limitation

The specification of the '759 patent teaches that "movable handle 40 includes a finger loop 41 which has an aperture 42 defined therethrough which enables a user to grasp and move the handle 40 relative to the fixed handle 50." '759 patent at 8:40-43. The opening (or aperture) through which a user may insert her fingers "is dimensioned to facilitate grasping the handle." Id. at 13:46-48. The claimed "finger loop" consists of a closed curved structure that surrounds the back and front of the inserted fingers, enabling the user to pull the movable handle to close the jaws of the device and to push the handle to open the jaws. Id. at 23:22-31 (claim 1), 8:17-23,

[10] The Court also notes that Covidien never limited the scope of the claimed invention to endoscopic forceps in the course of prosecuting the '759 patent.

8:39-43, 13:46-48, Figs. 13, 30, 37. The Court construed "a finger loop" to mean "a closed curve for receiving one or more fingers." Doc. No. 144 at 17.

Covidien concedes that the shepherd's hook design of the movable handle in the Enseal X1 device does not literally practice the "finger loop" limitation. Doc. No. 262 at 11. Covidien argues instead that the shepherd's hook practices the "finger loop" limitation under the doctrine of equivalents. Id. It does not.

"Infringement under the doctrine of equivalents requires the patentee to prove that the accused device contains an equivalent for each limitation not literally satisfied." Wi-Lan, Inc. v. Apple, Inc., 811 F.3d 455, 463 (Fed. Cir. 2016). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733 (2002). "An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." Catalina, 289 F.3d at 812. Whether an accused device infringes under the doctrine of equivalents is a question of fact. Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016).

The Federal Circuit "applies two articulations of the test for equivalence." Voda v. Cordis Corp., 536 F.3d 1311, 1326 (Fed. Cir. 2008); see also Warner-Jenkinson, 520 U.S. 17, 40 (1997) (different articulations of the test for equivalence "may be more suitable to different cases, depending on their particular facts."). "Under the insubstantial differences test, '[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial.'" Id. (quoting Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir 2004)); see also Valmont Indus., Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1043

(Fed. Cir. 1993) ("An equivalent under the doctrine of equivalents results from an insubstantial change which, from the perspective of one of ordinary skill in the art, adds nothing of significance to the claimed invention.").

Alternatively, "[t]he function-way-result test provides that 'an element in the accused device is equivalent to a claim limitation if it performs substantially the same function in substantially the same way to obtain substantially the same result.'" Tomita Techs. USA, LLC v. Nintendo Co., 681 Fed. Appx. 967, 971 (Fed. Cir. 2017) (quoting Voda, 536 F.3d at 1326). "The function, way, result inquiry focuses on an examination of the claim and the explanation of it found in the written description of the patent." Plastic Omnium Advanced Innovation & Research v. Donghee Am., Inc., 943 F.3d 929, 938 (Fed. Cir. 2019) (internal quotation marks and citation omitted). But the Court is not limited to considering the features described in the patent when analyzing the comparative functions. Intendis GmbH v. Glenmark Pharms., Inc., 822 F.3d 1355, 1362 (Fed. Cir. 2016) ("The relevant inquiry is what the claim element's function in the claimed composition is to one of skill in the art, and a fact finder may rely on extrinsic evidence in making this factual determination.") (citing Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1425 (Fed. Cir. 1994)).

Covidien has not shown by a preponderance of the evidence that the shepherd's hook practices the finger loop claim limitation under either articulation of the test for equivalence. There are meaningful differences between the finger loop and the shepherd's hook handle, which are grasped and released differently, and which "receive" the user's fingers differently.[11] The

[11] The patent defines the finger loop's purpose in part as pushing forward to open the jaws. The purpose of the shepherd's hook on the Enseal X1 is also to push forward to open the jaws but only when extra force is needed, for the jaws otherwise open on their own by means of a spring mechanism. The Court notes these differences but does not decide the issue of equivalence on this basis as the parties did not rely on this distinction to differentiate between the two handle designs.

finger loop handle is grasped by inserting one or more fingers into the opening of the closed loop. The handle with the shepherd's hook design is grasped by holding on to the non-movable part of the handle and sliding one or more fingers against the curved, distal part of the handle from below or the side. Because it is closed, the finger loop receives and contains the user's fingers, and the user must pull her fingers out of the finger loop when extricating her hand from the handle. To remove her fingers from the handle with the shepherd's hook design, the user simply slips her fingers out of or away from the hook.

The user's fingers are also held differently in the two handles. By virtue of being a closed loop, the finger loop handle can contain the user's fingers when the handle is held in every direction—right side up or upside down, and backwards- or forwards-facing. The shepherd's hook handle does not "contain" the user's fingers in the same way. It cannot hold the fingers when the instrument is upside down because there is nothing to contain the fingers in place. The shepherd's hook handle does not even hold the user's fingers in place when the instrument is right side up. The fingers below the end of the end of the hook do not even contact the hook part of the handle; those above the end of the hook are "held in place" by the user, not by the handle.

Forward pressure is also not exerted in the same way in the two types of handles. The finger loop allows the user to use all of her fingers in the loop to push the handle forward and to exert forward pressure with all her contained fingers—that is, if the user's fingers press or slide down on the distal side of the handle, the closed loop will still contain them and will continue to enable the exertion of forward pressure. In contrast, the shepherd's hook design allows only for some of the fingers—those fitting behind the hook—to push the handle forward. The user must hold those fingers in place. If the user's fingers slide down (they cannot press down) the handle will not contain them and they will exert no forward pressure.

For these reasons, the Court concludes that the shepherd's hook design does not perform substantially the same function, in substantially the same way, with substantially the same result as the finger loop, and that it is not insubstantially different from the shepherd's hook design.

The Court is also not persuaded that Ethicon's own patents and litigation filings support a different conclusion. Covidien points to U.S. Patent No. 8,623,027 ("the '027 patent"), assigned to Ethicon, which discloses a shepherd's hook handle design, and teaches that a closed loop is an alternative embodiment of that design. Doc. No. 262 at 15; see also '027 patent at 12:14-45 ("In one embodiment, the trigger 120 comprises an elongated trigger hook 124, which defines an aperture 126 between the elongated trigger hook 124 and the trigger 120. The aperture 126 is suitably sized to receive one or multiple fingers of the user therethrough. . . . In another embodiment, the geometry of the trigger forms a fully closed loop which defines an aperture suitably sized to receive one or multiple fingers of the user therethrough.").

Covidien also points to "a separate patent litigation between the parties involving a shepherd's hook design patent," Doc. No. 262 at 15, in which Ethicon's expert opined on whether alternative non-patented designs could produce the same or similar functional capabilities as the patented design such that the patented design would be deemed ornamental—i.e., not dictated by function—and therefore eligible for design patent protection. In that litigation, "Ethicon's expert opined that a nearly closed loop handle would function better than Ethicon's patented shepherd's hook handle because the closed loop handle would 'provid[e] a surer grip and more surface area against which to apply force in a distal direction.'" Doc. No. 268 at 8-9 (quoting PTX-012 at 42).

Neither Ethicon's '027 patent nor its design patent litigation filings support the conclusion that a shepherd's hook design meets the claimed "finger loop" limitation of the '759 patent. Leaving aside that the '759 patent does not itself disclose that an alternative embodiment of the

finger loop is an open shepherd's hook design, Ethicon's '027 patent merely supports the conclusion that the functions of the shepherd's hook design might be met by a fully closed loop. It does not support the reverse—that the functions of a fully closed loop may be achieved by a shepherd's hook design, except perhaps at a very high level of generality. That two different designs may both enable a user to push and pull the handle to open and close the jaws does not mean they are equivalent for purposes of infringement. And indeed, Ethicon's design patent filings make clear that the finger loop handle provides functionality the shepherd's hook design lacks by providing "a surer grip and more surface area against which to apply force in a distal direction." Doc. No. 268 at 8-9.

The Court therefore concludes that Covidien has not shown by a preponderance of the evidence that the shepherd's hook design of the Enseal X1 satisfies the "finger loop" limitation.

3. The "of unitary construction" and "drive flange" limitations

The remaining two disputed claim limitations of the '759 patent—"a movable handle **of unitary construction** having a finger loop positioned towards a first end thereof, [and] **a drive flange** positioned towards a second end thereof…"—are of a piece. By its own terms, claim 1 of the '759 patent requires that the "unitary construction" of the movable handle include "a drive flange." The Court construed "of unitary construction" to mean "constructed as a single unit." Doc. No. 144 at 15.

As for the "drive flange" limitation, the specification teaches that:

> As best seen in FIG. 14, movable handle 40 is selectively moveable about a pair of pivot pins 29a and 29b from a first position relative to fixed handle 50 to a second position in closer proximity to the fixed handle 50 which, as explained below, imparts movement of the jaw members 110 and 120 relative to one another. The movable handle include[s] a clevis 45 which forms a pair of upper flanges 45a and 45b each having an aperture 49a and 49b, respectively, at an upper end thereof for receiving the pivot pins 29a and 29b there through and mounting the upper end of the handle 40 to the housing 20. . . . . Each upper flange 45a and 45b also includes

> a force-actuating flange or drive flange 47a and 47b, respectively, which are aligned along longitudinal axis 'A' and which abut the drive assembly 150 such that pivotal movement of the handle 40 forces actuating flange against the drive assembly 150 which, in turn, closes the jaw members 110 and 120. For the purposes herein, 47a and 47b which act simultaneously on the drive assembly are referred to as "driving flange 47."
>
> . . .
>
> As mentioned above, the movable handle 40 includes clevis 45 which forms upper flanges 45a and 45b which pivot about pins 29a and 29b to pull the reciprocating sleeve 60 along longitudinal axis 'A' and force during [sic] flange 47 against the drive assembly 150 which, in turn, closes the jaw members 110 and 120.

'759 patent at 8:49–9:1, 13:26-31 (emphasis added). The specification thus discloses that the drive flanges (elements 47a and 47b) are part of the upper flanges (elements 45a and 45b), and that the upper flanges pivot about the link pins to pull the reciprocating sleeve and force the drive flange against the drive assembly to close the jaw members. Id. at 8:61-66.[12] In light of these disclosures, the Court construed the term "drive flange" to mean "a force-actuating and projecting rib or rim." Doc. No. 144 at 15.

The claimed drive flange functions by being positioned on the end of the movable handle that is operably coupled to the drive sleeve to impart movement thereto. Id. at 16 (construing "operably coupled to the drive sleeve" as "linked to the drive sleeve for imparting reciprocating movement thereto"); '759 patent at 14:25-30; see also Doc. No. 258 (1/15 Tr.) at 115:2-116:20. The Court determined that "the claim itself requires neither a drive assembly nor direct physical contact between the drive flange and any particular component." Doc. No. 144 at 16. And it determined that "the phrase 'operably coupled,' which appears two other times in claim 1, plainly

[12] Although the asserted claims of the '759 patent require only "a drive flange" (singular) and not "drive flanges" (plural), the parties appear to agree that what the patent refers to as "a drive flange" actually refers to two halves or sides of a single component. Their dispute over whether the accused devices practices the drive flange limitation does not implicate the singular versus plural use of the claim term.

and ordinarily (and specifically in the context of the '759 patent) encompasses components which are either directly or indirectly linked to one another." Id.

Covidien contends that the raised structures projecting from each side of the movable handle—which structures Covidien calls "ribs" and Ethicon calls "bosses"—practice the "drive flange" limitation, and that therefore the movable handle on the Enseal X1 also meets the "of unitary construction" limitation. Doc. No. 262 at 17-22. Ethicon does not dispute that the movable handle of the Enseal X1 is "constructed as a single unit," except insofar as it disputes that the handle, as constructed, includes "a drive flange" because it disputes that the raised structures projecting from each side of the movable handle practice the "drive flange" limitation either literally or under the doctrine of equivalents. Doc. No. 264 at 12-17. Ethicon disputes both that the raised structures are "ribs" and that they are "force-actuating and projecting." Id. at 12-15.

Trial revealed that the parties disagree about the proper interpretation of both parts of the Court's claim construction—that is, they disagree over what constitutes a "rib" and over what "force-actuating and projecting" means. The Court must therefore resolve these disputes before proceeding to its infringement analysis. GE Lighting Sols., LLC v. AgiLight Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) ("[P]arties in patent cases frequently stipulate to a construction or the court construes a term, only to have their dispute evolve to a point where they realize that a further construction is necessary."); O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it.").

After reviewing the evidence and arguments submitted by the parties, the Court determines that a "rib" is "material added to strengthen or reinforce a part."[13] The Court agrees with Covidien that for present purposes, the term "rib" is not limited to "thin strips," as Ethicon contends. See, e.g., Doc. No. 264 at 13. In construing the claim term "a drive flange," the Court determined that "the phrase 'projecting rib or rim' appears to aptly describe all of the other components which the '759 patent also calls 'flanges.'" Doc. No. 144 at 15. And indeed, the term "flange" covers a number of different components in the patent including the drive flange, locking flange, and pivot flange. '759 patent at 8:54-62, 9:5-15, 10:57-61, 13:50-51, Figs. 10, 13, 14 (depicting and describing upper flanges [45a and 45b], a flange [90] at the lower end of the movable handle, a pivot flange [118] on a jaw member, a locking flange [44], and a flange [154] on the drive ring). See id., Fig. 14. As depicted in Figure 14, neither the locking flange nor the pivot flange are "thin strips." Requiring the drive flange to be a thin strip would read this embodiment out of the patent and is contrary to the Court's construction.

Extrinsic evidence supports the Court's determination that a "rib" is "material added to strengthen or reinforce a part" and is not limited to "thin strips." The Glossary of CAD/Drafting Terms defines a rib as "a closed section of material usually added to reinforce a part without adding excessive material or weight," DTX-437 (Glossary of CAD/Drafting Terms) at 9, and Ethicon's own expert defined "ribs" in another litigation as "generally" referring to "raised portions created by adding material during the design process," DTX-524 at ¶ 99. The Court therefore rejects Ethicon's proposed requirement that "ribs" be limited to "thin, protruding strips" and interprets the term to mean "material added to strengthen or reinforce a part." On this basis, the Court

[13] In so doing, the Court notes that the parties' competing interpretations of the term "rib" reveal they agree that a rib is material added to a component to strengthen or reinforce it but disagree over the shape the added material must take.

concludes that the raised structures on the movable handle of the Enseal X1 are "ribs" under the Court's claim construction.[14]

The only remaining question, then, is whether the ribs on the movable handle of the Enseal X1 are "force-actuating and projecting."[15] The specification teaches that the handle of the patented invention transmits the force from the user's grasp of the movable handle through the handle, up to the drive flanges, which are on the end of the handle, to the link pin via the pinhole, and from the link pin to the link that is operably coupled to the drive sleeve. '759 patent at 8:49–9:1, 13:26-31. The parties agree that the raised structures on the movable handle of the Enseal X1 add strength to the part of the movable handle that comes into contact with the link pin. Doc. No. 263 ¶¶ 89-90; Doc. No. 265 ¶¶ 138-139. Nevertheless, they disagree over whether this is sufficient to satisfy the "force-actuating and projecting" requirement of the Court's construction of the "drive flange" claim term. Trial revealed that the parties' dispute centers on whether, to satisfy the "force-actuating and projecting" requirement, the claimed drive flanges must be the only components that transmit the force exerted by the user's hand on the movable handle to the drive sleeve or whether other components may also participate in the transmission of that force.

The Court concludes that the claim limitation at issue requires that the claimed drive flanges are the only components that transmit the force exerted by the user's hand on the movable handle to the drive sleeve. The specification refers to the drive (or "driving") flange as the

[14] The Court therefore need not address Covidien's alternative argument that in the event the Court determines that the raised structures do not satisfy the "rib" portion of the Court's construction, the raised structures nevertheless satisfy the "drive flange" limitation under the doctrine of equivalents. See Doc. No. 262 at 21-22.

[15] The ribs are "operably coupled to the drive sleeve." As the Court determined, the raised structures need not be in direct contact with the drive sleeve to be "operably coupled" to it. Indirect contact is sufficient. Doc. No. 144 at 16. Here, the ribs indirectly contact the drive sleeve by virtue of their contact with the link pin.

"actuating flange," '759 patent at 8:65, and discloses no other component that transmits to the drive sleeve the force exerted by the user's hand on the movable handle, see generally id. And both parties' experts agreed—and the Court found—that if the drive flanges 47a and 47b on the patented instrument were removed, the device would not function because no force would be transmitted from the movable handle to the drive sleeve. Doc. No. 238 (9/27 Tr.) at 110:24-111:15; Doc. No. 260 (1/16 Tr.) 37:6-18. The Court therefore concludes that that the claimed drive flange is the only part of the movable handle of unitary construction that transmits to the drive sleeve the force exerted by the user on the handle and interprets "force-actuating and projecting" accordingly.

Covidien has identified the raised structures on the movable handle of the Enseal X1, which the Court agrees are "ribs," as the claimed "drive flanges." Doc. No. 262 at 17-22. Covidien has identified no other structures on or portions of the movable handle of the Enseal X1 as the claimed "drive flanges." See id. The issue before the Court, therefore, is whether the ribs are "force-actuating and projecting" in the sense contemplated by the patent. After reviewing the evidence presented, the Court determines that they are not.

Both parties' experts agreed—and the Court found—that removal of the ribs from the movable handle of the Enseal X1 device did not prevent the transmission of force from the handle to the jaw members, though the parties disagreed over whether the same amount of force was transmitted before and after removal.[16] Even if less force were transmitted when the ribs were removed, however, it would not be enough to sustain a determination that the ribs are "force-

[16] Ethicon's expert testified that it was the same amount of force, though he admitted that he did not measure whether there was any difference in the amount of force transmitted before and after the raised structures were removed. Doc. No. 239 (10/1 Tr.) at 43:21-44:13. Covidien's expert testified that the removal of the raised structures weakened the handle component of the device, and noted that the that modified device has not been used "under load," as typically required "to make certain that the modified device would be reliable in surgery" and to verify that the modified handle would not fracture "under repeated usage." Doc. No. 258 (1/15 Tr.) at 102:14-106:3.

actuating and projecting" in the sense contemplated by the patent. The Court does find—as Covidien urges—that the Enseal X1, as sold and used, has ribs that are operably coupled to the drive sleeve, and that these ribs strengthen and reinforce the edge of the pinhole with which they, and the part of the handle on which they sit, come into contact. But the fact that their removal does not prevent the transmission of force from the handle to the drive sleeve means that they cannot satisfy the requirement that they be "force-actuating and projecting" because they are not the only part of the movable handle of unitary construction that transmits the force exerted by the user on the handle to the drive sleeve.

Covidien contends that the removal of the ribs only shows that the force they normally transmit from the user's grasp had been redistributed elsewhere onto the handle. Doc. No. 262 at 21. That the force has been so redistributed, Covidien argues, does not mean that the ribs on the actual accused device—the Enseal X1, as sold and used—do not satisfy the requirement that they be "force-actuating and projecting." Id. The Court is not persuaded by this argument. Accepting that the force is redistributed to other parts of the handle when the ribs are removed necessarily means (and the Court finds based on the evidence at trial) that the parts of the handle other than the ribs through which the link pin moves also transmit force when the ribs are removed (as well as when they are present). This, in turn, means that the ribs are not the only portion of the handle to transmit force exerted by the user.

The Court therefore concludes that Covidien has not shown by a preponderance of the evidence that the ribs on the movable handle of the Enseal X1 device are "force-actuating and projecting," and therefore has not shown that the movable handle of the Enseal X1 device contains the claimed "drive flanges." And, because the movable handle of the Enseal X1 device does not

contain the claimed "drive flanges," the accused device also does not meet the limitation that the movable handle be "of unitary construction."

B. '759 Patent – Invalidity

Ethicon contends the asserted claims of the '759 patent are obvious in light of U.S. Patent No. 6,419,675 ("Gallo") (PTX-088) in view of one or more of: WO 02/080795 ("Dycus '795") (PTX-099), Dycus '799 (PTX-100),[17] and WO 02/058544 ("Witt") (PTX-098).[18] "A party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a person of ordinary skill would have selected and combined and modified the subject matter of the references in the manner of the claimed invention, with a reasonable expectation of success." Orexo AB, v. Actavis Elizabeth LLC, 903 F.3d 1265, 1271 (Fed. Circ. 2018).

Ethicon's primary reference, Gallo, does not teach several of the limitations recited in independent claim 1 of the '759 patent. First, Gallo does not teach the claimed movable and fixed jaw member configuration, disclosing instead a design with four pliable jaw members. PTX-088, Fig. 2 (elements 16, 18, 20, 22); id. at 3:14-30. Second and relatedly, the four pliable jaw members

[17] WO 02/080795 ("Dycus '795") (PTX-099) and WO 02/080799 ("Dycus '799") (PTX-100) were published on October 17, 2002; there is no dispute they are prior art to the '759 patent under pre-AIA 35 U.S.C. § 102(a). Dycus '795 is a continuation-in-part of Dycus '799. Because the specifications of the two references are nearly identical, PTX-099, PTX-100, Doc. No. 239 (10/1 Tr.) at 51:2-9, Doc. No. 258 (1/15 Tr.) at 152:2-11, the parties refer to them in tandem. The Court follows the same practice.

Dycus '795 and '799 were identified as prior art and incorporated by reference in the '759 patent specification. '759 patent at 3:35-40. Dycus '795 and '799 do not disclose a movable handle of unitary construction that includes a drive flange and a locking flange but instead disclose a "four bar mechanical linkage" design in which the drive flange, locking flange, and movable handle are separate components. The Patent Office determined that the '759 patent claims are not obvious over the "four-bar mechanical linkage" design disclosed in Dycus '799 because the separate components were not part of a movable handle of unitary construction. JTX-004 at COVENSL0048004-05, 48012, 48014-22; see also Doc. No. 258 (1/15 Tr.) at 154:16-156:17.

[18] WO 02/058544 ("Witt") (PTX-098) published on August 1, 2002; there is no dispute that it is prior art to the '759 patent under pre-AIA 35 U.S.C. § 102(a).

in Gallo are moved from the open to the closed positions by a tubular sheath mechanism, not by a drive sleeve mechanism as claimed in the '759 patent. PTX-088, Fig. 2 (element 12); id. at 3:14-30; '759 patent at 23:14-21.

Third, Gallo does not disclose a finger loop handle but instead discloses a straight lever handle, which does not enable the user to push forward on a surrounding structure to open the jaw members. PTX-088, Fig. 6 (element 24).

Fourth, Gallo does not disclose a locking flange positioned on a movable handle of unitary construction in the way recited by independent claim 1 of the '759 patent—that is, disposed between the finger loop and the drive flange. '759 patent, claim 1 ("a movable handle of unitary construction having a finger loop positioned towards a first end thereof, a drive flange positioned towards a second end thereof, and a locking flange disposed between the finger loop and the drive flange").[19] Gallo instead discloses a "safety arc" component that impedes actuation of the knife trigger (or "ear") and advancement of the cutter before the jaw members are in the closed position. PTX-088, Fig. 5 ("safety arc" element 107), Fig. 4 ("ear" element 28). The "safety arc" disclosed in Gallo is a separate component from the movable handle. See PTX-088 at Fig 5 (elements 24 and 107).

The issue before the Court is whether Ethicon has shown by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to modify Gallo in such a way as to produce the device claimed in the '759 patent. In undertaking this determination, the Court is mindful of the repeated admonition by the Supreme Court and the Federal Circuit to avoid

[19] The features that Ethicon's expert witness identified as the claimed locking flange on Gallo's movable handle is part of the same structure he identified as the drive flange, and it is in any event not situated between the drive flange and the bottom of the handle, where the finger loop is located in the '759 patented device. PTX-088, Figs. 4-6 (element 92); Doc. No. 239 (10/1 Tr.) at 58:10-17; Doc. No. 258 (1/15 Tr.) at 144:23-151:9.

hindsight bias when conducting an obviousness inquiry. See, e.g., KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning."); Orexo, 903 F.3d at 1271 ("Judicial hindsight must be avoided."). The Court is also mindful of the Federal Circuit's guidance that the fact that redesigns and substitutions of prior art patented devices may be envisioned—and indeed that various benefits of such redesigns and substitutions may be imagined—is not evidence that such redesigns would have been obvious to a person or ordinary skill in the art at the time of the invention, or that such a person would have been motivated to make them. See, e.g., id. at 1272-1273 ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.") (quoting In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984)).

Modifying the device disclosed in Gallo to arrive at the '759 patent device would have required a substantial re-design of the Gallo device, including re-designing at least the jaw members, shaft and shaft assembly, the mechanism used to close the jaw members, and the movable handle. Doc. No. 258 (1/15 Tr.) at 137:25-151:20. The Court is not persuaded that a person of ordinary skill in the art at the time of the invention would have been motivated to modify Gallo's four pliable jaw member configuration and tubular sheath mechanism to arrive at the configuration of one movable and one fixed jaw member actuated by a drive sleeve mechanism as claimed in the '759 patent. Nor is it persuaded that such a person would have been motivated to further modify Gallo to substitute its straight level handle with a finger loop handle (or with the thumb ring handle disclosed in Witt, see PTX-098, Fig. 2 (element 30)), or to redesign the handle so that it has a drive flange and a locking flange positioned as recited in the asserted claims of the '759 patent.

Ethicon points to no disclosure in the cited prior art or in any other source that suggests the desirability—at the time of the invention—of redesigning the jaw members, shaft and shaft assembly, the mechanism used to close the jaw members, and the movable handle of Gallo in the ways required to produce the device covered by the claims of the '759 patent. Unsupported testimony by Ethicon's expert witness that such design changes would have improved the device is not evidence of a motivation to undertake those changes at the time of the invention.[20] Indeed, Ethicon's expert witness did not even attempt to quantify the amount of time or resources it would have taken to modify the Gallo device to produce the device claimed in the '759 patent, Doc. No. 239 (10/1 Tr.) at 59:8-60:6, much less point to anything in the prior art suggesting the desirability of redesigning Gallo in the various ways required to produce the device covered by the asserted '759 patent claims, Doc. No. 258 (1/15 Tr.) at 137:25-151: 20.

The Court therefore concludes that Ethicon has not met its burden to show, by clear and convincing evidence, that the asserted claims of the '759 patent are obvious over any of the prior art references on which Ethicon relies.

[20] For example, Mr. Leinsing testified that "the motivation" to modify Gallo's instrument, which has two pairs of clamping arms (i.e., both pairs of jaws move), so that only one of the pairs of jaws moved while the other pair was fixed, was that such a redesign would provide a fixed surface with which to elevate tissue and thereby minimize "knife/blade trap." Doc. No. 238 (9/27 Tr.) at 120:8-121:16. And he testified that person of ordinary skill in the art would have been motivated to replace Gallo's straight lever handle with a finger loop handle not only to prevent slippage of fingers off of the handle but also to allow for opening the jaws by pushing outward on the handle—something the Gallo straight lever handle does not allow a user to do. Id. at 121:17-122:16. But such testimony is not evidence of a motivation to modify—it is only evidence that Mr. Leinsing was able, with the full benefit of hindsight, to articulate how Gallo might have been improved by redesigning it to be more like the device claimed in the '759 patent. It does not show or even suggest that a person of ordinary skill in the art at the time of the invention would have been motivated to improve Gallo in the way Mr. Leinsing identified, much less that such a person would have sought to do so by redesigning Gallo to resemble the '759 patented device, rather than by attempting to achieve the benefits Mr. Leinsing enumerated in some other way.

C. The '310 Patent – Claim Construction

Claim 1 of the '310 patent recites that "when the jaw members are disposed in the second [i.e. closed or "clamped"] position, a plane is formed between the opposing sealing surfaces." '310 patent at 6:21-23. It also recites that the plane is offset from the longitudinal axis in a direction opposite to that of the pivot pin.[21] Id. at 6:23-24. During claim construction proceedings, Ethicon argued that because a gap exists between the claimed opposing jaw members when they are closed, and because basic geometry dictates that an unlimited number of planes exist within such a three-dimensional space, the "plane" limitation renders the claim indefinite. Doc. No. 121 at 28-30. Covidien disagreed and proposed construing the claimed plane to mean "an imaginary flat surface bisecting the opposing sealing surfaces when grasping tissue." Doc. No. 118 at 22-25. Finding that "Ethicon raise[d] substantial questions of indefiniteness," the Court deferred construing the plane limitation "until the close of all discovery, when a fuller record [was] available." Doc. No. 144 at 14. At trial, Ethicon proposed that in the event the Court did not determine that the claim is indefinite, the "plane" term should be construed to mean "a flat surface that coincides with opposing sealing surfaces that are in contact with each other." Doc. No. 264 at 23.

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). As the Court noted during the parties' closing arguments, Ethicon and Covidien agree that the claimed "plane" is the mid-plane between the opposing jaw members when

[21] As noted supra at n.5, the parties agree that the limitation in claim 1 that "a plane is formed between the opposing sealing surfaces" means the same thing and has the same scope as the limitation in asserted independent claim 16 that "a plane is formed between the opposed sealing surfaces." The parties have stipulated that the two claim phrases "rise or fall together in terms of the indefiniteness challenge." Doc. No. 238 (9/27 Tr.) (Stipulation) at 15:2-16:2.

they are in the closed position; they disagree only over whether the sealing surfaces of the jaw members must come into contact with one another when the jaw members are in that position. Doc. No. 272 at 124:25–125:14. After reviewing the evidence submitted at trial and the parties' arguments, the Court concludes that the "plane" term is not indefinite, and that a person of ordinary skill in the art would understand the claimed plane to be the mid-plane between the sealing surfaces when the jaws are in the closed position. The only remaining issue for purposes of construing the claim is whether the sealing surfaces must come into contact with one another when the jaw members are in a closed position.[22]

The asserted claims of the '310 patent are silent on this issue. Ethicon nevertheless argues that the plane limitation must be construed to require the sealing surfaces to come into contact with one another for two reasons. First, Ethicon argues that unless the sealing surfaces come into contact with one another, the claimed "plane" is indefinite because a gap contains an infinite number of planes and the patent offers no guidance to determine which of these is the claimed plane. Doc. No. 264 at 22-23. The Court is not persuaded. It credits Dr. Taylor's testimony that a person of ordinary skill in the art at the time of the invention would have understood that the claimed plane is the mid-plane between the sealing surfaces when the jaw members are in the closed position, even if that position left a gap between the sealing surfaces. See Doc. No. 235 (9/24 Tr.) at 62:2-25. Indeed, the only figure in the patent showing the jaw members in a closed (or "clamped") position shows a gap between the sealing surfaces of the jaw members. '310 patent, Fig. 3; see also Doc. No. 121-25 ¶ 51 (Ethicon's expert noting that "Fig. 3B represents a scenario where a gap exists between the opposed sealing surfaces when the jaw members are in the

[22] The parties agree that if the claimed sealing surfaces must come into contact with one another, the Enseal X1 does not infringe. Doc. No. 272 at 125:8-14

second/clamped position.") (citing '310 patent at 3:43-48, Fig. 3B). Other figures in the patent support this conclusion. See, e.g., '310 patent, Figs. 1, 2. These show dots on the sealing surfaces of the jaw members. Id. Although the dots are not described or claimed, a person of ordinary skill in the art at the time of the '310 patent would have understood that the dots are stop members, which prevent the sealing surfaces from coming into contact with each other because such contact would cause the electrosurgical device to short-circuit and cease functioning.

Ethicon also contends that the patent specification itself discloses that the sealing surfaces must come into contact with each other. Doc. No. 264 at 23-24. Again, the Court is not persuaded. The specification does disclose that "during the movement to the closed and grasping configuration, the distal tips 116 and 126 of jaw members 110 and 120, respectively, come into contact with one another first and the closure pressure transferred to the jaw members 110 and 120 by drive assembly 150 deflects the proximal portion of jaw member 110 into contact with jaw member 120 thereafter." '310 patent at 4:46-52. The Court understands this disclosure to be explaining that, in the described embodiment, the jaw members are so designed that when they are in the process of clamping down on grasped tissue, the distal ends of the jaw members close first, before the proximal ends of the jaw members do. Indeed, the specification goes on to explain that "[m]anufacturing the jaw members 110 and 120 in this fashion creates a more uniform pressure distribution along the jaw members 110 and 120 which enhances a tissue seal." Id. at 4:52-55. The quoted passage, which refers to one of several embodiments, does not support the contention that the patent specification discloses that the sealing surfaces must touch each other when the jaw members are in the closed position.

There are also two disclosures in the patent that, taken together, suggest that in one embodiment, the claimed plane limitation is only met when the sealing surfaces come into contact

with each other. In the first, the specification teaches that "[i]n another embodiment, the plane formed between the opposing sealing surfaces is offset a distance 'Y' relative to the longitudinal axis, where 'Y' is preferably in the range of about 0.005" to about 0.025"." '310 patent at 2:4-7 (emphasis added). The second reads: "[w]ith continued reference to FIGS. 3A-3B, fixed jaw member 120 may be configured such that sealing surface 122 of jaw member 120 lies below longitudinal axis 'A.' Sealing surface 122 may be positioned a distance 'Y' below the longitudinal axis 'A' where 'V' [sic] is preferably in the range of about 0.005" to about 0.025"." Id. at 4:6-11 (emphasis added).

Taken together, these disclosures support the conclusion that the patent contemplates an embodiment in which the claimed plane coincides with the meeting of the opposing sealing surfaces. In the disclosed embodiment, the same variable, "Y," represents both the distance (a) between the longitudinal axis and the claimed plane and (b) between the longitudinal axis and the lower sealing surface. Given that the claimed plane limitation is only met when the jaw members are in the closed position and that, in this embodiment, the plane coincides with the lower sealing surface, it follows that, in this embodiment, the sealing surfaces are required to touch.[23] That said, nothing in the patent suggests that the claims are limited to this embodiment, and reading the claims to be so limited would read out the embodiment disclosed in Figure 3B, which shows a gap between the sealing surfaces when the jaw members are in the closed position.

The Court therefore construes the "plane" term as "the plane that bisects the gap between the sealing surfaces when the jaw members are in the closed position," and rejects Ethicon's

[23] Such an embodiment is consistent with a monopolar electrosurgical device. Ethicon agrees that the claims of the '310 patent encompass monopolar electrosurgical devices and that having the sealing surfaces in such instruments touch does not pose a shorting risk. Doc. No. 268 at 16.

reading of the "plane" limitation as requiring that the sealing surfaces touch when the jaw members are in the closed position.

D. The '310 Patent – Infringement

The parties agree and the Court finds the sealing surfaces of the jaw members in the Enseal X1 do not touch when the jaw members are in the closed position. For purposes of the infringement inquiry, therefore, the only issue is whether Covidien has met its burden of showing by a preponderance of the evidence that the plane that bisects the gap between the sealing surfaces of the jaw members when they are in the closed position is below the longitudinal axis. After reviewing the evidence submitted at trial and the parties' arguments, the Court concludes that Covidien has not met its burden of proving that the Enseal X1 practices the "plane" limitation, and therefore has failed to prove that the Enseal X1 infringes the asserted claims of the '310 patent.

Covidien relies on two principal sources of evidence to support its infringement argument: (a) fact and expert testimony relating to a CAD Assembly File of the Enseal X1; and (b) expert testimony relating to photographic evidence of Enseal X1 devices. Both suffer from significant shortcomings.

1. Evidence pertaining to the CAD Assembly File

Ethicon's lead engineer on the Enseal X1 and its in-house patent counsel both testified during their pre-trial depositions that in the course of their non-infringement analysis, they had located the longitudinal axis of the shaft on a CAD Assembly File drawing of the Enseal X1, and that the longitudinal axis they had located was closer to the upper sealing surface than it was to the lower sealing surface of the opposing jaw members when they were in the closed position. Examining the same CAD Assembly File, Covidien's expert witness calculated that the mid-plane between the sealing surfaces was .00145 inches below the longitudinal axis. Nevertheless, this

evidence is insufficient to prove that actual Enseal X1 devices practice the claimed "plane" limitation.

As an initial matter, the CAD Assembly File may be suitable for certain types of measurements—such as the location of the longitudinal axis of a shaft whose width is stable along its length—but is not reliable for mapping the precise spatial relationships of components of a device whose dimensions are not stable, or a reliable basis for determining precise distances between components of manufactured devices.

Moreover, while the CAD Assembly File may closely approximate the dimensions of physical Enseal X1 devices, it is not itself a physical device, and as such, does not reflect the manufacturing tolerances for such devices. The manufacturing tolerances pertaining to the Enseal X1 device range between .001 and .005 inches. Applying such manufacturing tolerances to the offset calculated by Covidien's expert witness (.00145 inches) easily reduces the offset to zero or even less than zero.

There is still another problem with using the CAD Assembly File to determine the precise distances between components of the Enseal X1 device. The CAD Assembly File misrepresents the spatial relationships of the components in the manufactured devices in at least one respect: it shows that the top of the distal pin extends above the upper sealing surface when in actual devices the top of the distal pin rests right on, but does not extend beyond, that upper sealing surface. The finding that the top of the distal pin extends above the upper sealing surface in the CAD Assembly File but not on actual Enseal X1 devices undermines the reliability of using the CAD Assembly File to measure the precise distances at issue in this case such that the Court declines to do so. It further underscores the importance in this case of examining and measuring actual devices to determine whether they practice the claimed offset configuration.

In light of this evidence, and in the absence of any measurements of actually manufactured, physical Enseal X1 devices, evidence of measured distances on the CAD Assembly File is insufficient to show that Enseal X1 devices practice the claimed "plane" limitation. For these same reasons, the statements of the two Ethicon witnesses are similarly limited, based as they are, on a visual inspection of the CAD Assembly File, which is not reliable evidence that the mid-plane is below the longitudinal axis in actually manufactured Enseal X1 devices.

2. Evidence pertaining to photographs of Enseal X1 devices

Covidien did not present evidence of measurements made on any physical Enseal X1 devices but presented evidence of measurements made on photographs of four such devices. Using a single reference point on each photograph, Covidien's expert witness located the longitudinal axis on the photographs of each of the four devices, and determined, based on his visual inspection, that in each case the longitudinal axis was above the mid-plane, though he did not calculate the distance of the offset he observed.

Covidien has not shown, and the Court has not found, that Covidien's reliance on photographs of Enseal X1 devices to show that the claimed plane is below the longitudinal axis on actual Enseal X1 devices is reliable. As an initial matter, although all methodologies are subject to error, Covidien presented no evidence regarding the error rate attributable to the use of photographic evidence to measure the miniscule distances at issue here, or to the degree of potential measurement distortions to be expected from the positioning of the devices photographed. Dr. Durfee did testify that he estimated that his identification of the location of the longitudinal axis on the photographs themselves was subject to a margin of error of plus or minus .002 inches, Doc. No. 235 (9/24 Tr.) at 166:25-167:4, but that margin of error does not reflect the additional error rate attributable to use of photographs in the first instance, or to the potential for

distortion attendant upon the positioning of the photographed devices, especially where, as here, the reliability of the evidence depends on the accurate identification of perfectly parallel lines.

Aside from failing to show that using photographs to measure the miniscule distances at issue here is a reliable approach, several problems attend the photographic evidence itself. First, Dr. Durfee, used only a single reference point on the photographic images to identify the longitudinal axis. In the absence of evidence showing that the devices were positioned in such a way as to ensure that the longitudinal axis Dr. Durfee identified was perfectly parallel with the upper and lower surfaces of the shaft, the use of a single reference point to identify the longitudinal axis introduces the problem that the axis he identified may have been drawn on an angle, with the consequence that it appears to be higher or lower at its end point than it really is. Given the tiny size of the claimed offset configuration at issue, even very small deviations from a perfectly horizontal axis can make the difference between apparent infringement and non-infringement. Dr. Durfee's use of a single reference point to identify the location of the longitudinal axis therefore undermines the reliability of that identification. This conclusion is supported by the testimony of Ethicon's expert witness that the longitudinal axis Dr. Durfee identified on each of the four photographs was drawn at a slight angle—one sufficient to negate any finding that the longitudinal axis, correctly identified, is above the mid-plane of the sealing surfaces. Doc. No. 235 (9/24 Tr.) at 216:21-25.

Second, Dr. Durfee's estimated margin of error—plus or minus .002 inches—is sufficiently large to eclipse the distance between the longitudinal axis and the claimed "plane," which, under the Court's claim construction, is the mid-plane between the sealing surfaces of the jaw members when they are in the closed position. There is no dispute that the gap between the sealing surfaces when the jaw members are in the close position is .008 inches. This means that the mid-plane is

.004 inches from the top sealing surface, and .004 inches from the bottom sealing surface. Unless Dr. Durfee's identified longitudinal axis is less than .002 inches from the top sealing surface, his estimated margin of error (plus or minus .002 inches) negates any determination that the longitudinal axis is above the mid-plane. Because Dr. Durfee did not measure the distance of the longitudinal axis from the top sealing surface, and because a mere visual inspection involving such small distances is inherently problematic and unreliable for establishing infringement, there is insufficient evidence from which to conclude that the photographs show that the mid-plane is below the longitudinal axis.

The Court has also considered the totality of the separate pieces of evidence Covidien submitted, but in this case the sum of the parts is not greater than the individual constituent pieces. The Court therefore concludes that Covidien has not shown by a preponderance of the evidence that the Enseal X1 practices the claimed plane limitation and that Covidien has therefore failed to prove that the Enseal X1 infringes any of the asserted claims of the '310 patent.

E. The '310 Patent – Invalidity

Title 35 U.S.C. 102(a)(1) provides that "[a] person shall be entitled to a patent unless the claimed invention was patented, [or] described in a printed publication before the effective filing date of the claimed invention." "A finding of anticipation requires clear and convincing evidence that 'each and every element is found within a single prior art reference, arranged as claimed.'" ATEN Int'l Co. v. Uniclass Tech. Co., 932 F.3d 1364, 1368 (Fed. Cir. 2019) (quoting Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1294 (Fed. Cir. 2015)). See also Nobel Biocare Servs. AG v. Instradent USA, Inc., 903 F.3d 1365, 1375 (Fed. Cir. 2019) ("A prior art document may anticipate a claim if it describes every element of the claimed invention, either expressly or inherently."); Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984)

("This court has repeatedly stated that the defense of lack of novelty (i.e., 'anticipation') can only be established by a single prior art reference which discloses each and every element of the claimed invention."). "Testimony concerning anticipation must typically 'explain in detail how each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory.'" ATEN, 932 F.3d at 1368 (quoting Schumer v. Lab. Comput. Sys., Inc., 308 F.3d 1304, 1315-16 (Fed. Cir. 2002)).

The parties have stipulated that the cited prior art references—U.S. Patent Application Publication No. 2003/0229344 ("Dycus '344") (PTX-076), U.S. Patent No. 6,056,735 ("Okada") (PTX-087), and WO2008/040485 ("Geiselhart") (PTX-101)—disclose all but the claimed "plane" limitation at issue in the asserted independent claims of the '310 patent.[24] Doc. No. 238 (9/27 Tr.) at 58:10-59:16, 63:19-64:14, 70:15-21. All three prior art references are directed to surgical devices. None of them claim or describe the offset configuration claimed in the '310 patent—i.e., a pivot pin offset in one direction from the longitudinal axis and a plane formed between the opposing sealing surfaces of the jaw members when they are in the closed position offset in a different direction from the longitudinal axis. See generally PTX-076, PTX-087, PTX-101. Nor do any of the cited prior art references discuss the problem addressed by the '310 patent—to improve the mechanical advantage and uniform pressure distribution across the jaw members to enable better tissue sealing. '310 patent at 3:55-58, 4:42-45, 4:52-54. Instead, Ethicon relies on certain figures in each reference to support its argument that the offset configuration—the claimed "plane" limitation—is anticipated or obvious.[25]

[24] The parties have also stipulated that the prior art references at issue disclose all the limitations of the asserted dependent claims except that the parties agree that Okada does not anticipate dependent claim 4. Doc. No. 238 (9/27 Tr.) at 65:10-14.

[25] Ethicon contends that the claimed offset configuration is anticipated by all three references and that it is also obvious over Dycus '344. Doc. No. 264 at 27.

For the reasons that follow, the Court concludes that Ethicon has not met its burden of showing by clear and convincing evidence that the cited figures (or the prior art references more generally) anticipate the claimed "plane" limitation or render it obvious.

It is well settled that "arguments based on drawings not explicitly made to scale in issued patents are unavailing." Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1149 (Fed. Cir. 2005); see also Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951, 956 (Fed. Cir. 2000) ("Under our precedent, . . ., it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."); In re Wright, 569 F.2d 1124, 1127 (C.C.P.A. 1977) ("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value."). Here, none of the cited prior art references discloses that the figures at issue are drawn to scale or that they define the precise proportions of components or the relationships among components of the claimed devices. See generally Dycus '344 (PTX-076), Okada (PTX-087), and Geiselhart (PTX-101). To the contrary, there is clear evidence that the figures in the cited prior art references were not drawn to scale and do not define the precise dimensions of components or the precise spatial relationships among them.

1. Dycus '344

Ethicon points to Figure 39D of Dycus '344 as disclosing the claimed offset configuration. Doc. No. 264 at 27-29. Ethicon's argument is unavailing. Aside from the lack of any disclosure in Dycus '344 that the figures are drawn to scale, Figure 39D, which shows one of several embodiments of the patented device in the closed position, is facially inconsistent with Figure 39C, which shows the same embodiment of the patented device in the open position:

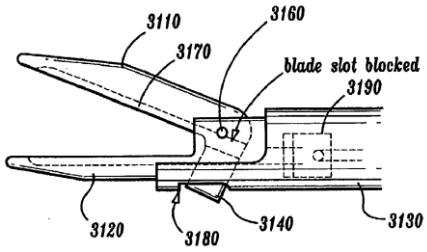


FIG. 39C

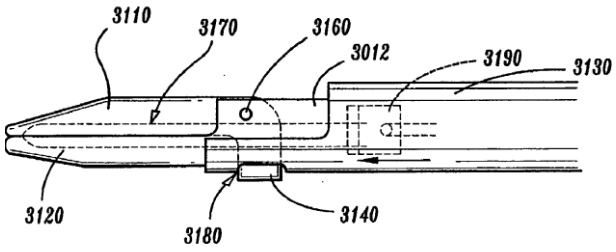


FIG. 39D

PTX-076, Figs. 39C and 39D. The two figures are inconsistent with one another in several respects, including the location of shaft 3012 in relation to outer sleeve 3130, the location of knife blade 3190 in relation to knife slot 3170 and pivot pin 3160, and the size of the knife blade in comparison to the knife slot through which the knife must travel. These inconsistencies support the conclusion that a person of ordinary skill in the art would not view the figures in the '344 patent as accurately representing the precise dimensions of claimed components or as disclosing specific spatial relationships among the components with the degree of accuracy required to show that Figure 39D discloses the claimed offset configuration. Doc. No. 241 (10/3 Tr.) at 7:7-14:12.

The deposition testimony of Mr. Sean Dycus, a named inventor on the Dycus '344 reference, does not resolve these inconsistencies. At his deposition, Mr. Dycus was asked to locate the pivot pin, the longitudinal axis, and the plane between the sealing surfaces on Figure 39D. He did so without first reading the specification, and he mistakenly identified element 3130, not element 3012, as the shaft. He then drew a horizonal line at the midpoint of element 3130 to identify the longitudinal axis:

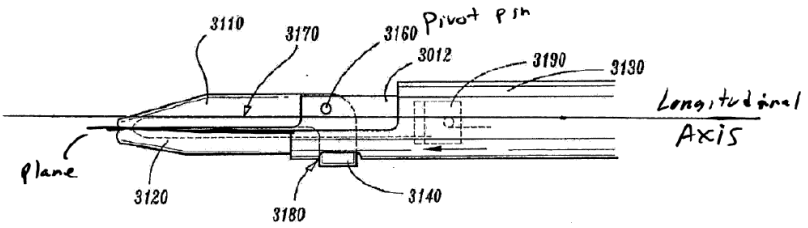


FIG. 39D

PTX-077 (Dycus '344, Fig. 39D annotated by Mr. Dycus).

There is no disclosure in Dycus '344 that elements 3130 and 3012—the outer tube and the shaft, respectively—are necessarily coaxial, i.e., that they share the same horizonal axis, but Ethicon contends that it would have been obvious to arrange elements 3130 and 3012 to make them coaxial. Doc. No. 264 at 29 (citing expert testimony that such coaxial arrangements reduce "slop" between inner and outer tubes and enable the use of less costly, off-the-shelf parts). Even so, Mr. Dycus's identification of the horizonal axis on Figure 39D would still be unreliable because the figure itself is not drawn to scale and is facially inconsistent with Figure 39C. Its inconsistency with Figure 39C alone shows that Figure 39D was not drawn to reflect the precise dimensions of the disclosed components or their spatial relationships with each other. Because it is these very dimensions and spatial relationships that are at issue in the claimed offset configuration, reliance on Figure 39D is not sufficient to constitute clear and convincing evidence that the claimed offset configuration is anticipated by or obvious over the Dycus '344 reference.

2. Okada

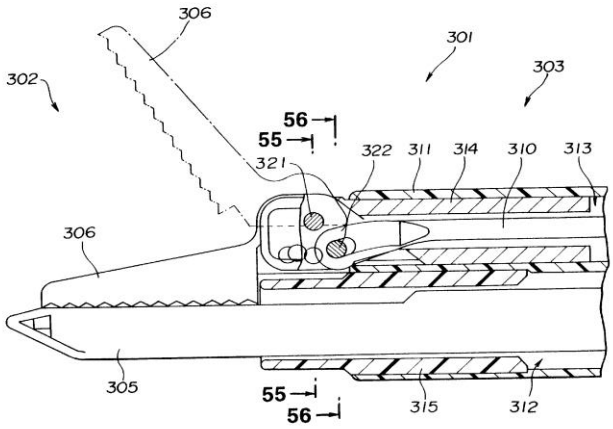
Ethicon points to Figures 4, 6, and 7B of Okada, representing the first embodiment of the patented invention, and Figure 54, representing the seventeenth embodiment of the patented invention, to support its argument that Okada discloses the claimed offset configuration. Doc.

No. 264 at 30. The Court is not persuaded that the figures in Okada reliably disclose the precise dimensions of the represented components or the precise spatial relationships among them.

Like the figures in Dycus '344, the figures in Okada on which Ethicon relies are also unreliable for purposes of demonstrating a disclosure of the claimed offset configuration by clear and convincing evidence not only because there is nothing in the written description suggesting that the figures were drawn to scale but because various figures contain inconsistencies that show they were not drawn to scale and were not meant to represent precise spatial relationships, like those at issue in the claimed "plane" limitation.

For example, Figure 54 of Okada includes the same element—holding member 306—in both an open and a closed position, but the holding member is drawn smaller in the open position than it is in the closed position, which would lead a person of ordinary skill in the art to understand that Okada's figures are not drawn to scale or meant to reflect precise proportions.

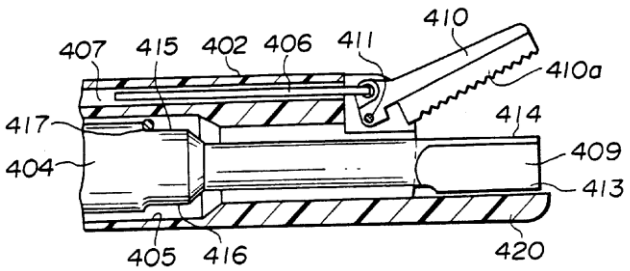
FIG.54



PTX-087, Fig. 54; see also Doc. No. 241 (10/3 Tr.) at 27:20-29:12.

Another figure of Okada, Figure 64, shows a sealing plane that is coincident with the longitudinal axis of its shaft, which is contrary to the '310 patent claims:

FIG.64



PTX-087, Fig. 64; Doc. No. 241 (10/3 Tr.) at 30:6-31:8. Ethicon did not rely on Figure 64, which represents a different embodiment from those on which it did rely,[26] but there is no disclosure in the written specification suggesting that the various embodiments are distinguishable from one another with reference to the relative locations of the longitudinal axis and the claimed "plane." See generally PTX-087. Nor is there any disclosure suggesting that the relative locations of the longitudinal axis and the sealing plane in the various embodiments of the Okada invention were even contemplated. See id.

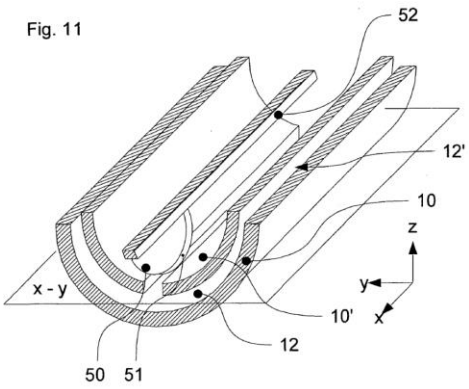
The Court is therefore not persuaded that a person of ordinary skill in the art would infer that the varying locations of the longitudinal axis and sealing plane in the various figures in Okada could be read as representing meaningful differences in those embodiments, rather than just inconsequential differences in how the figures were drawn. The Court is instead persuaded that a person of ordinary skill in the art would conclude that the figures in Okada do not reliably reflect precise dimensions and spatial relationships like those at issue in the claimed offset configuration of the "plane" limitation in the asserted claims of the '310 patent.

[26] Together with Figures 63 and 65, Figure 64 represents the eighteenth embodiment of the claimed invention in Okada. PTX-087 at 39:64-65. To support its anticipation defense, Ethicon relied only on figures representing the first and seventeenth embodiments of Okada. Doc. No. 264 at 30.

3. Geiselhart

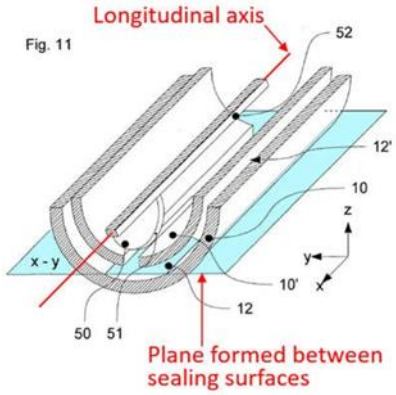
Ethicon also relies on certain figures in Geiselhart to support its contention that the claimed offset configuration at issue in the '310 patent is anticipated. Doc. No. 264 at 30-31. Like the Dycus '344 and Okada references, the written specification of the Geiselhart reference does not disclose a plane formed between opposing sealing surfaces offset in a direction opposite from that of the pivot pin in relation to the longitudinal axis of the shaft, or that the figures in the reference are drawn to scale. See generally PTX-101.

Figure 11 of Geiselhart discloses a tubular shaft (24), a blade (51), a guide wire (52), and a fixing plane "x-y":



PTX-101, Fig. 11; id. at 6-7, 10-11.

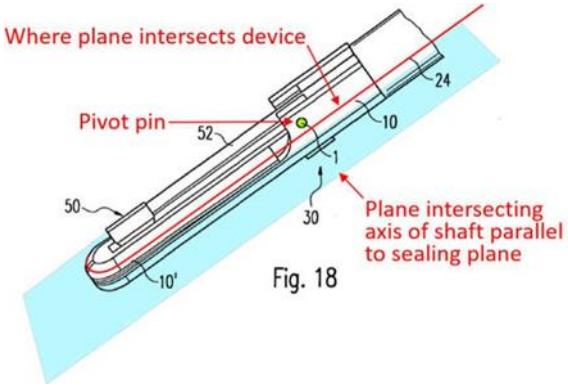
At trial, Ethicon's expert witness, Mr. Leinsing, identified the sealing plane with the x-y axis and the longitudinal axis as coincident with element 52—the guide wire:



Doc. No. 238 (9/27 Tr.) at 71:18-72:7. But Mr. Leinsing's identification of the longitudinal axis with the guide wire in Figure 11 is contrary to the written specification, which discloses that "[t]he curvature of the guide wire 52 is such that, if the proximal end of the guide wire extends parallel to the tubular shaft 24, the distal end of the free guide wire 52 is curved downward and the blade 51 is located at least partially beneath the fixing plane x-y." PTX-101 at 11.

Thus, Geiselhart does not disclose that the guide wire (52) is located on the same plane as the longitudinal axis of the tubular shaft (24). Id., Fig. 12; see also Doc. No. 241 (10/3 Tr.) at 35:4-37:12, 38:12-39:5. To the extent the figure appears to suggest otherwise, it is an unreliable guide to Geiselhart's disclosures.

So too with respect to Figure 18, on which Ethicon also relies:



PTX-101, Fig. 18 (annotated). The written description discloses that "[t]he rotation axis 1 lies substantially on the longitudinal axis of the mouth parts 10, 10'." PTX-101 at 12. Based on this disclosure, a person of ordinary skill in the art would understand that the rotation axis 1 would be located on the plane where the mouth parts 10 and 10' come together, Doc. No. 241 (10/3 Tr.) at 39:11-42:10, which is not what the figure shows.

Given the inconsistencies between the figures in Geiselhart and its written specification, the Court is persuaded that a person of ordinary skill in the art would understand that the figures

are not drawn to scale and do not define the precise proportions of the elements or their spatial relationships.

Ethicon's reliance on Geiselhart's disclosure that "placing the pivot pin above the jaw members helps to pull the tissue into the jaw members on closing," Doc. No. 264 at 31 (quoting PTX-101 at 7), is also unavailing. For one thing, although the specification of the '310 patent teaches that the offset configuration claimed by the '310 patent improves the mechanical advantage and uniform pressure distribution across the jaw members to enable better tissue sealing, it does not disclose that this advantage comes from "pulling the tissue into the jaw members on closing." For another, the position of the pivot pin in relation to the longitudinal axis is only one part of the claimed offset configuration. The disclosure Ethicon cites is silent as to the relative locations of the longitudinal axis and the sealing plane.

One further point bears mention. Ethicon argues that even if the figures in Dycus '344, Okada, and Geiselhart are not precisely drawn to scale, they reliably reveal the spatial relationships among the components of the illustrated devices because the figures in these references are drawn with sufficient detail to enable a person to make the claimed inventions. Doc. No. 265 ¶ 337 (citing Doc. No. 239 (10/1 Tr.) at 115:20-24, 122:1-5). The Court is not persuaded by this argument. It may well be that the cited references contain sufficient detail to enable a person to make the claimed inventions, but that does not mean that they contain sufficient—and accurate—detail to serve as clear and convincing disclosures of the specific offset configuration claimed in the '310 patent. Given that the references themselves do not contemplate the relative locations of the longitudinal axis and the sealing plane, and that the figures are not drawn to scale or with the precision required to show the claimed offset configuration, the fact that the disclosures are enabling does not mean that the figures disclose a limitation—the claimed offset configuration—

that does not appear to add anything to the inventions claimed or described in any of the cited references.

The Court concludes that the figures in the cited prior art references do not constitute clear and convincing evidence of anticipation or obviousness of the plane limitation in the asserted claims of the '310 patent, and that Ethicon has therefore failed to prove that the asserted claims of the '310 patent are invalid.

IV. CONCLUSION

For the foregoing reasons, the Court determines that: (1) Ethicon has failed to meet its burden to establish that any of the asserted claims of either United States Patent No. 9,241,759 or United States Patent No. 8,323,310 is invalid, and (2) Covidien has failed to meet its burden to establish that the Enseal X1 infringes any of the asserted claims of either of these two patents. Within fourteen days, the parties shall file a proposed form of judgment encompassing all claims in this litigation.[27]

SO ORDERED.

/s/ Leo T. Sorokin
Leo T. Sorokin
United States District Judge

[27] The Court has reached one conclusion from presiding over this case for the past several years that merits mention. At all times during the pendency of this matter, counsel for both Covidien and Ethicon vigorously advocated for their clients, remaining singularly focused on advancing their clients' positions, while never indulging litigation's ever-present temptation to sidetrack into denigration of the opposition. Counsel conducted themselves with professionalism and courtesy throughout the litigation, while at the same time presenting their positions forthrightly, clearly, crisply, and civilly. Covidien and Ethicon were well-served by their counsel, as was the Court. The Court also notes that the briefs containing hot links to the exhibits proved of substantial assistance and suggests counsel consider such submissions in future litigations, as will the Court.