UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ETHICON ENDO-SURGERY, INC., *et al.*,	:	Case No. 1:11-cv-871
	:	
	:	Judge Timothy S. Black
Plaintiffs,	:	
	:	
vs.	:	
	:	
COVIDIEN, INC., *et al.*,	:	
	:	
Defendants.	:	

ORDER RESOLVING MOTIONS FOR SUMMARY JUDGMENT (Docs. 184, 186, 188, 192)

This civil action is before the Court on the Plaintiffs Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (collectively, "Ethicon")'s motion for summary judgment of infringement (Doc. 186) and the parties' responsive memoranda (Docs. 199, 210); and Defendants Covidien Sales LLC, Covidien LP, and Covidien Inc. (collectively, "Covidien")'s motion for summary judgment of invalidity and non-infringement of U.S. Patent No. 9,168,055 (Doc. 188) and the parties' responsive memoranda (Docs. 201, 208). Also before the Court are Ethicon's motion for summary judgment of absence of acceptable and available non-infringing alternatives (Doc. 184) and the parties' responsive memoranda (Docs. 203, 209); and Covidien's motion for partial summary judgment precluding lost profits damages (Doc. 192) and the parties' responsive memoranda (Docs. 198, 207).

I. BACKGROUND

The devices at issue are ultrasonic instruments used in open and laparoscopic surgical procedures to cut and coagulate tissue and vessels, thereby helping to control bleeding and achieve hemostasis. Ethicon manufactures a line of ultrasonic surgical devices under the "Harmonic" brand. Ethicon's products use blades oscillating at extremely high speeds to make surgical procedures easier and safer, reducing damage to surrounding tissue, causing less bleeding, and generally allowing for better surgical outcomes than other methods of incision. Ethicon holds a portfolio of patents covering its Harmonic line. Covidien manufactures a laparoscopic, ultrasonic dissection device sold under the name "Sonicision." Ethicon contends that the Sonicision device infringes on Ethicon's U.S. Patent No. 9,168,055 (the "'055 Patent")

This case has a long procedural history before this Court. Ethicon initially filed suit against Covidien in 2011 alleging violation of several patents. Following discovery, the Court granted summary judgment in favor of Covidien on the issues of both noninfringement of the patents at issue and invalidity of certain patents. (See Docs. 130, 131, 132, 133, 134). On appeal, the Federal Circuit Court of Appeals reversed this Court's rulings in part, holding that none of the patents at issue were invalid, but upholding the Court's findings of noninfringement as to some of the patents. *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312 (Fed. Cir. 2015).

Following the Federal Circuit's ruling, Covidien filed a separate suit seeking a

declaratory judgment of noninfringement of six of Ethicon's patents. Ethicon filed a counterclaim alleging infringement of seven of its patents. That action was consolidated with the current action. Subsequently, the parties resolved and mutually agreed to dismiss all claims from each party relating to all patents, except for the '055 Patent.

Ethicon contends that Covidien has infringed the '055 Patent. Covidien claims that the '055 Patent is invalid for lack of written description, is invalid for obviousness, that the Sonicision device does not infringe on the '055 Patent because the Sonicision device exerts clamping pressure outside of the range claimed by the '055 Patent, and that six asserted claims[1] of the '055 Patent are not infringed because the Sonicision device does not apply a predetermined force or pressure.

II. UNDISPUTED FACTS[2]

A. The '055 Patent

The current dispute between Ethicon and Covidien relates to the validity and

[1] The six claims are 1, 2, 4, 5, 8, and 14, which include the requirement that the clamping arm exert a "predetermined" force or pressure. While Ethicon maintains that the Sonicision device infringes on these claims, Ethicon does not base its motion for summary judgment of infringement on these six claims. (Doc. 186 at 4).

[2] Pursuant to the Standing Order of the Court, Ethicon and Covidien filed Statements of Proposed Undisputed Facts and responses to the proposed statements for their respective motions. The Court's statement of facts set forth here incorporates the facts undisputed by the parties and the facts confirmed by the Court upon review of the citations to the evidentiary record provided by the parties. (*See* Ethicon's Statement of Undisputed Facts ("ESUF"): Docs. 186-1 and 201-1 at 98–185, Docs. 200 and 208-1; Covidien's Statement of Undisputed Facts ("CSUF"): Doc. 190, Doc. 201-1; Ethicon's Damages Statement of Undisputed Facts ("EDSUF"): Doc. 184-1, Doc. 2014; Covidien's Damages Statement of Undisputed Facts ("CDSUF"): Doc. 194, Doc. 198-1).

infringement of the ‘055 Patent, titled “Ultrasonic Surgical Shears and Method for Sealing a Blood Vessel Using Same.” The ‘055 patent is a direct continuation of the U.S. Parent No. 8,460,326 (the “‘326 Patent”), which is a direct continuation of U.S. Patent No. 8,182,501 (the “‘501 Patent”). The ‘055, ‘326, and ‘501 Patents are members of the same patent family and have identical specifications. (ESUF at ¶ 7; CSUF at ¶¶ 8, 16). The claims of the ‘501 and ‘055 Patents differ in several ways, including: (1) the ‘501 Patent recites a pressure range of 60 to 210 pounds per square inch (“psi”), while the ‘055 Patent claims a range of 120 to 210 psi; (2) each claim of the ‘501 Patent recites a “predetermined force” but claims 9, 10, and 20–25 in the ‘055 Patent do not contain a “predetermined” limitation; (3) the ‘501 Patent uses means-plus-function language to describe the structure that limits the clamping force, while the ‘055 Patent recites a “spring.” (ESUF at ¶ 7).

The ‘055 Patent was filed on May 17, 2013 as Application No. 13/896,380. The ‘055 Patent was issued on October 27, 2015 and has a priority date of February 27, 2004, the filing date of U.S. Provisional Application No. 60/548,308. (ESUF at ¶ 6; CSUF at ¶¶ 6–7).

The Background of the Invention of the ‘055 Patent provides in part:

> Ultrasonic surgical instruments are known which include ultrasonic surgical shears having an ultrasonic surgical blade, a clamping arm operable to open and close toward the blade, a tissue pad attached to the clamping arm and including a 0.033 square-inch clamping surface area, and a device for exerting a 1.5 pound clamping force on the clamping arm

> which creates a clamping pressure of 45 psi (pounds per square inch) on a blood vessel which is positioned between the clamping surface area of the tissue pad and the blade. It is noted that the clamping surface area is the area where the blade and the tissue pad are in close proximity when the clamping arm is in a closed position. Exemplary devices are described in U.S. Pat. Nos. 5,322,055 and 6,325,811, the contents of which are incorporated herein by reference. The result of the ultrasonically-vibrating ultrasonic surgical blade and the clamping pressure on the blood vessel is a coaptation of the blood vessel (a bringing together of the walls of the blood vessel), a transection (a cutting) of the coaptated blood vessel, and a coagulation (a sealing) of the coaptated cut ends of the blood vessel. It is known that blood-vessel transection times can be decreased with the application of a higher clamping force. However, this is not done because conventional thought is that decreasing the blood-vessel transection time using a higher clamping force will lead to a degradation in coagulation performance (i.e., a lowering of the burst pressure of a sealed end of the transected blood vessel). Conventional ultrasonic surgical shears are not used on blood vessels larger than 3mm because the clamping force used is inadequate for proper coaptation.

(Doc. 202-3 ("'055 Patent"), col. 1:30-56).

The Summary of the Invention of the '055 Patent provides in part:

> Several benefits and advantages are obtained from one or more of the method and the embodiments of the invention. Exerting an ultrasonic surgical shears coaptation pressure from 60 psi to 210 psi provides for improved blood vessel sealing with shorter transection times on 3 mm or smaller blood vessels than conventionally is possible and provides for blood vessel sealing with acceptable transection times and burst pressures on blood vessels larger than 3mm, which is not conventionally possible. Applicants experimentally found that applying an ultrasonic surgical shears coaptation pressure ranging from 60 psi to 210 psi (corresponding to a fully-engaged clamping surface area of 0.033 square inches and a

> clamping force ranging from 2 to 7 pounds) on 4.5 mm to 5 mm diameter blood vessels resulted in successful blood-vessel sealing with transection times of 2 to 4 seconds and with burst pressure of generally 500 to 700 mmHg compared to a transaction [sic] time of over 9 seconds and a burst pressure of generally 100 mmHg for a 45 psi clamping pressure (corresponding to a fully-engaged clamping surface are of 0.033 square inches and a clamping force of 1.5 pounds). Applicants also experimentally found that applying an ultrasonic surgical shears coaptation pressure ranging from 120 psi to 180 psi (corresponding to a fully engaged clamping surface are of 0.033 square inches and a clamping force ranging from 4 to 6 pounds) on 5 mm to 7 mm diameter blood vessels resulted in successful blood-vessel sealing with transection times of 1.5 to 2.0 seconds and with burst pressures of generally 500 mmHg compared to a transaction [sic] time of generally 4.5 seconds and a burst pressure of generally 30 mmHg for a 45 psi clamping pressure (corresponding to a fully-engaged clamping surface are of 0.033 square inches and a clamping force of 1.5 pounds).

(*Id.*, col. 2:24–55).

While Ethicon contends that the Sonicision device infringes on claims 1, 2, 4, 5, 8, 9, 10, 14, and 20–25, Ethicon's motion is limited to claims 9, 10, and 20–25 of the '055 Patent. (ESUF at ¶ 40). Ethicon asserts that claims 9, 22, and 24 are representative of the claims asserted in this motion. (*Id.* at ¶ 41).[3]

Claim 9 of the '055 Patent reads:

> 9. An ultrasonic surgical shears comprising:

[3] Covidien does not dispute that "9, 22 and 24 of the '055 patent 'are representative of the claims asserted in this motion,' to the extent that claims 9, 22 and 24 do not recite "predetermined" force or pressure claim elements, as compared to claims 1, 2, 4, 5, 8, and 14, which are not asserted in Ethicon's summary judgment motion. Covidien otherwise disputes the characterization of claims 9, 22 and 24 as 'representative' of '055 patent claims 9–10 and 20–25." (Doc. 200 at ¶ 41).

a) an ultrasonic surgical blade;
b) a clamping arm operable to open and close toward the blade;
c) a tissue pad attached to the clamping arm; and
d) a spring for limiting an average clamping force, wherein the blade and tissue pad define a clamping surface area and the average clamping force provides for an average clamping pressure between and including 120 psi and 210 psi at the clamping surface area.

(Doc. 202-3 (‘055 Patent), col. 8:13-23).

Claim 22 of the '055 Patent provides:

22. An ultrasonic surgical shears comprising:
a) an ultrasonic surgical blade;
b) a clamping arm operable to open and close toward the blade;
c) a tissue pad attached to the clamping arm, wherein the blade and tissue pad define a clamping surface area when the blade and the tissue pad are in close proximity; and
d) a spring for limiting a clamping force, wherein the clamping force divided by the clamping surface area is between and including 120 psi and 210 psi on tissue disposed on the clamping surface area.

(*Id.*, col. 8:27–36).

Claim 24 of the '055 Patent provides:

24. An ultrasonic surgical shears comprising:
a) an ultrasonic surgical blade;
b) a clamping arm operable to open and close toward the blade;
c) a tissue pad attached to the clamping arm; and
d) a spring for transferring a clamping force, wherein the blade and tissue pad define a clamping surface area and wherein the spring transfers a clamping force to

> obtain a clamping pressure between and including 120 psi and 210 psi at the clamping surface area.

(*Id*., col. 8:27-36.)

On March 12, 2017, the parties agreed to a construction for the claim term "is pre-loaded" as follows:

Claim Term	**Construction**
is pre-loaded (claims 21, 23, 25)	possesses a loading force before use

(ESUF at ¶ 45).

On April 10, 2017, the Court entered an Order on Claim Construction construing two additional claim terms as follows:

Claim Term	**Construction**
spring (claims 1, 9, 14, 20–25)	no construction is necessary[4]
"predetermined average coaptation pressure" (claim 1) / "predetermined clamping force" (claim 14)	clamping (pressure/force) set in advance of operating the clamping arm or clamping (pressure/force) set by the user prior to operating the clamping arm.

(Doc. 176).

In discussing clamping pressures, the '055 Patent states: "The pressures discussed herein are pressures seen by tissue when the entire clamping surface area is in contact with the tissue. As previously mentioned, a clamping surface area is the area where the blade and tissue pad are in close proximity when the clamping arm is in a closed

[4] The Court noted that "[t]he ordinary meaning of the term 'spring' is apparent, and the inventor did not specifically define the term or disavow its customary meaning, either expressly or in context." (Doc. 176 at 9).

position." ('055 Patent, col. 4:23–27).

Below, Figure 2 of the '055 Patent depicts ultrasonic surgical shears (18), means (28) for exerting a clamping force on the clamping arm (22), tissue pad (24), and blade:

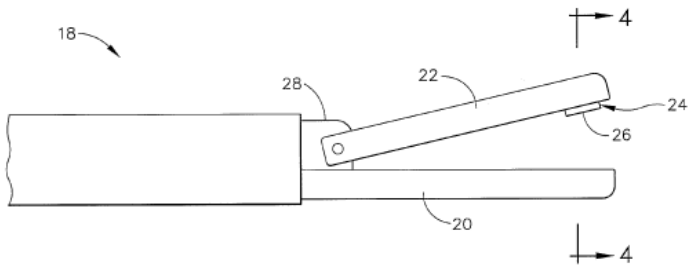


FIG. 2

(*Id.* at col. 4:33–37). In referencing Figure 2 of the '055 Patent, the 055 Patent specification states: "The ultrasonic surgical shears 18 also includes means 28 for exerting a clamping force on the clamping arm 22 creating a clamping pressure between and including 60 psi and 210 psi on tissue disposed between the tissue pad 24 and the blade 20." (*Id.*)

Below, Figure 3 of the '055 Patent depicts ultrasonic surgical shears (30), means (40) for limiting a user-applied clamping force on the clamping arm (34), tissue pad (36), and a blade (32):

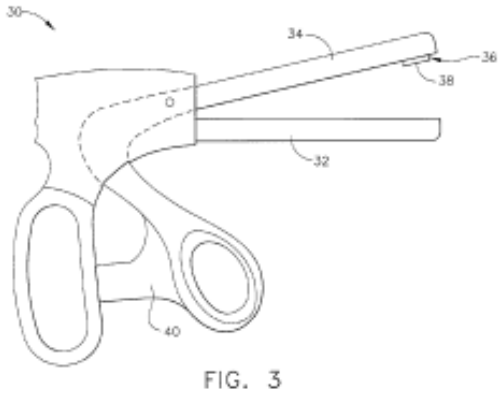


FIG. 3

(*Id.*, Fig. 3). In referencing Figure 3, the '055 Patent states: "The ultrasonic surgical shears 30 also includes means 40 for limiting a user-applied clamping force on the clamping arm 34 creating a clamping pressure between and including 60 psi and 210 psi on tissue disposed between the tissue pad 36 and the blade 32." (*Id.*, col. 5:4–8).

The below Figure 4 from the '055 patent shows a cross-sectional view of a tissue pad (26) and blade (20), with the maximum width of each denoted by the arrows "Wp" (for pad width) and "Db" (for blade diameter or width), respectively:

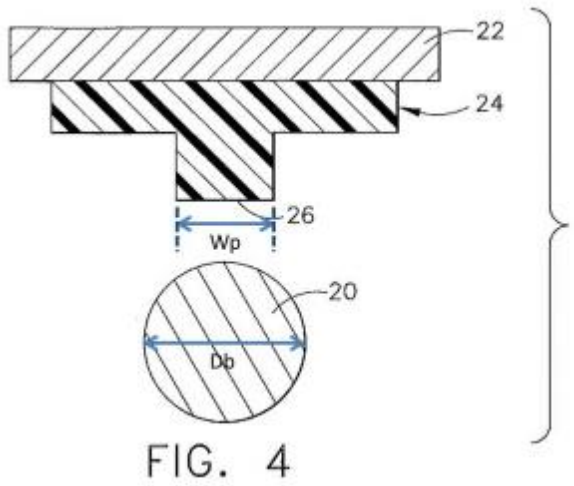


FIG. 4

(*Id.*, Fig. 4; ESUF ¶¶ 131–132).

Figure 5 of the ‘055 Patent also includes the following cross-sectional figure of an ultrasonic shears, which shows the blade (120), tissue pad (124), clamping surface area (127), and clamping arm (122):

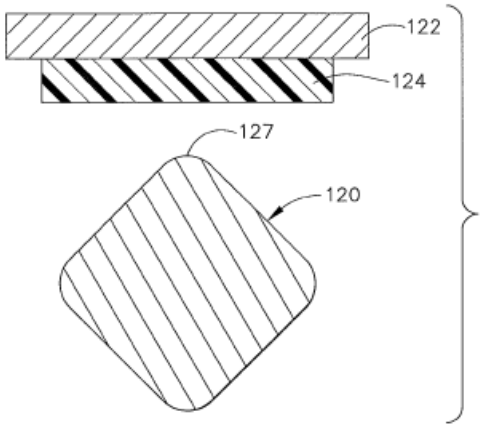
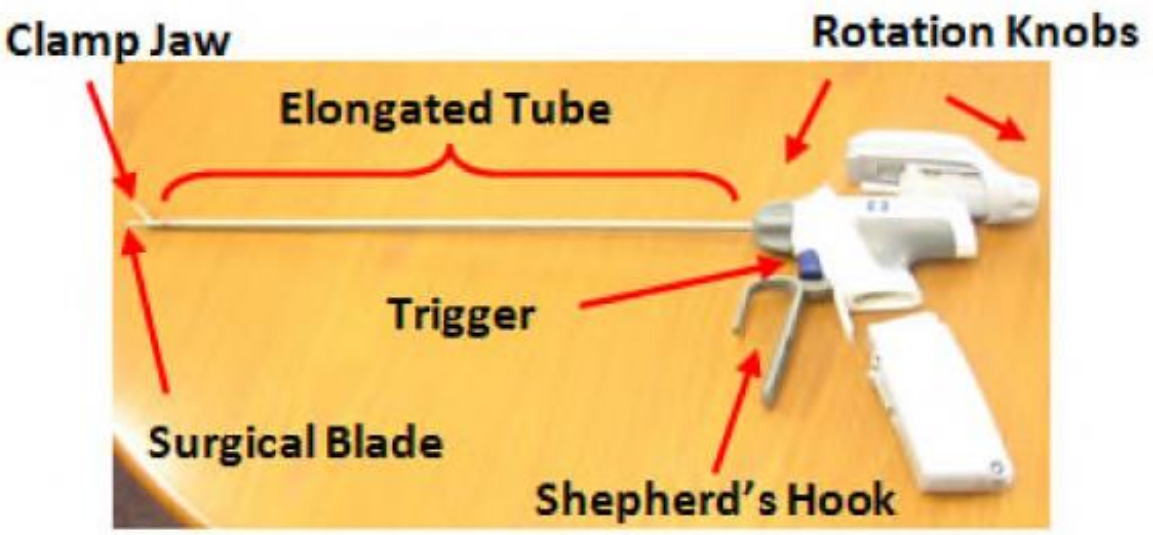


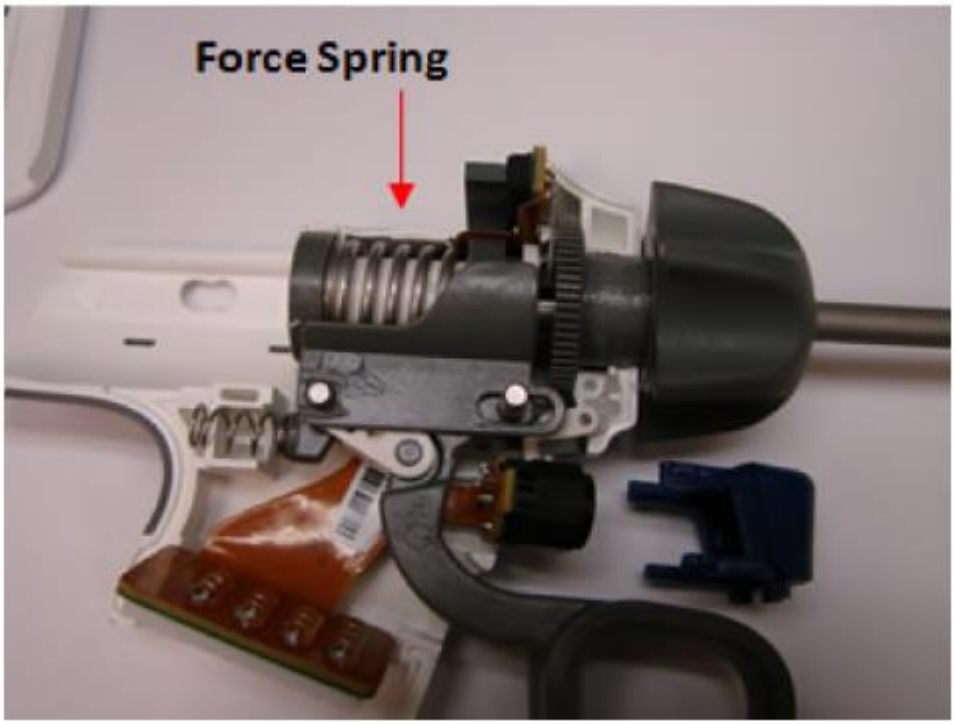
FIG. 5

(*Id.*, Fig. 5).

B. Sonicision Device

Covidien’s Sonicision devices at issue have the following products codes: SCD13, SCD26, SCD391, SCD396, and SCD48. (ESUF at ¶ 20). While the different product codes have different shaft lengths, for the purpose of these motions, these Sonicision devices are the same in all relevant aspects. (Id. at ¶ 21). As shown below, each Sonicision device includes a blade, a clamping arm, a wave guide within inner and outer tubes, a handle (in the form of a “Shepherd’s hook”), a force spring, a rotation knob, and an activation button.





(*Id.* at ¶ 18). In use, a physician operates the Sonicision device by pulling on the trigger to open and close the clamp arm, and applies ultrasonic energy through the use of the activation button. (*Id.*)

A cross-sectional view of Sonicision's blade and opposing tissue pad on the clamp arm is shown below:

Figure 1

(CSUF at ¶¶ 64–65).

At Covidien's expert's deposition, Dr. William Durfee identified what he considered to be Sonicision's "rounded tip" and "slanted side," which were considered in his calculation of clamping surface area.

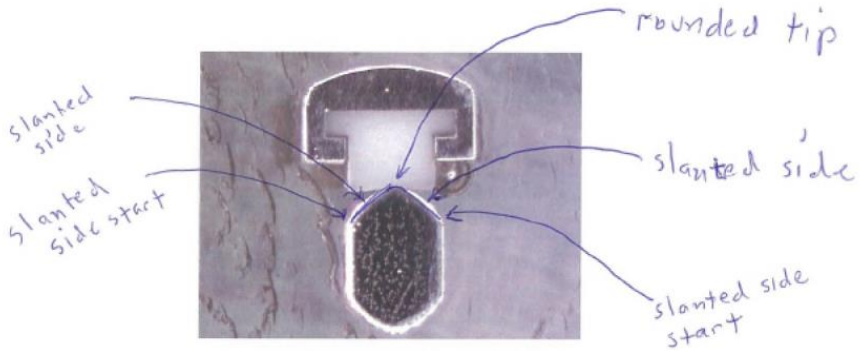


Figure 1

(ESUF at ¶ 105).

III. STANDARD OF REVIEW

A motion for summary judgment should be granted if the evidence submitted to the Court demonstrates that there is no genuine issue as to any material fact, and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); s*ee Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). The moving party has the burden of showing the absence of genuine disputes over facts which, under the substantive law governing the issue, might affect the outcome of the action. *Celotex*, 477 U.S. at 323. All facts and inferences must be construed in a light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

A party opposing a motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (1986).

"When reviewing cross-motions for summary judgment, [courts] must evaluate each motion on its own merits and view all facts and inferences in the light most favorable to the nonmoving party." *Appoloni v. United States*, 450 F.3d 185, 189 (6th Cir. 2006). "When a district court denies summary judgment to one party on the ground that it is granting summary judgment to another party, the denial of summary judgment is based on a legal conclusion rather than the district court's finding of a genuine issue of material fact." *Westfield Ins. Co. v. Tech Dry, Inc.* 336 F.3d 503, 506 (6th Cir. 2003).

On cross-motions for summary judgment on the same issue, "if there is no genuine dispute and one or the other party is entitled to prevail as a matter of law, the court will render judgment." 10A Fed. Prac. & Proc. Civ. § 2720 (4th ed.).

IV. INFRINGEMENT AND VALIDITY ANALYSIS (Docs. 186, 188)

Before addressing Covidien's argument that the '055 Patent is invalid, the Court will analyze whether the Sonicision devices infringe on the '055 Patent.

A. Infringement of the '055 Patent

Ethicon moves for summary judgment of infringement on claims 9, 10, and 20–25 of the '055 Patent. (Doc. 186). Covidien cross-moves for summary judgment of noninfringement of all claims of the '055 patent on the grounds that the Sonicision exerts clamping pressure outside of the claimed 120 to 210 psi pressure range, and additionally moves for summary judgment of noninfringement of claims 1, 2, 4, 5, 8, and 14 on the grounds that Sonicision does not practice the predetermined limitation recited in those claims. (Doc. 189 at 39–45).

Determining infringement consists of two steps. The Court must (1) first interpret the claim, and (2) then compare the properly construed claims to the alleged infringing device. *SafeTCare Mfg., Inc. v. Tele-Made, Inc.*, 497 F.3d 1262, 1268 (Fed. Cir. 2007). To establish infringement of a patent, every limitation set forth in a claim must be found in an accused product or process exactly or by a substantial equivalent. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989) (citing *Corning Glass Works v. Sumitomo*

Elec. U.S.A., Inc., 868 F.2d 1251, 1259 (Fed. Cir. 1989). Thus, if the accused product fails to meet even a single claim limitation, then there can be no literal infringement as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). The motion of an accused infringer for summary judgment on the ground of non-infringement of a patent may be granted where the patentee's proof is deficient in meeting an essential part of the legal standard for infringement. *Johnston*, 885 F.2d at 1577 (citing *Townsend Eng'g Co. v. HiTec Co*., 829 F.2d 1086, 1089 (Fed. Cir. 1987)).

Ethicon is entitled to summary judgment of infringement if it shows that there is no genuine dispute of material fact that every limitation in the contested claims is found in the Sonicision device. Covidien is entitled to summary judgment of noninfringement if Ethicon has failed to proffer evidence to support a finding that a limitation of the asserted claim was met by the structure in the Sonicision device.

a. Infringement by Sonicision – Clamping Pressure

Ethicon contends that the '055 Patent represents an important advancement in the field of ultrasonic surgical devices because the inventors of the '055 Patent discovered that using higher clamping pressures in the claimed range of 120 to 210 psi, in contrast to the 60 to 210 psi range included in the '501 Patent, led to fast and effective vessel sealing, including for larger vessels. ('055 Patent, col. 2:24–55). All of the asserted claims of the '055 Patent require clamping pressure less than or equal to 210 psi at the clamping surface area. Ethicon argues that Covidien's Sonicision devices infringe on the

‘055 Patent because Sonicision exerts clamping pressures in the 120 to 210 psi pressure range. Covidien, on the other hand, argues that the Sonicision devices exert clamping pressure outside of the claimed 120 to 210 psi pressure range.

The parties’ experts agree that the Sonicision device includes each element of claims 9, 10, 20–25 except for the clamping pressure limitation. (ESUF ¶ 63). There is no dispute that clamping pressures claimed in the ‘055 Patent are calculated by dividing clamping force by the relevant clamping area. (CSUF at ¶¶ 59–60). There is no dispute that clamping force must be measured at the midpoint of the clamping surface area. (CSUF ¶¶ 117–18, 122–23). Dr. Durfee, Covidien’s expert, testified that he agreed with and used the force measurements of Karl Leinsing, Ethicon’s expert. (Doc. 186-3 (“Durfee Tr.”) at 76:15–77:3) There is no dispute that the claimed clamping pressures are measured when the clamping arm and blade are in a closed position. (CSUF ¶¶ 118–19, 121, 124). The only dispute between the parties relates to the relevant clamping surface area. (Doc 186 at 11; Doc. 189 at 35). Indeed, the parties even agree on the length measurements of the clamping surface area (ESUF at ¶ 95); the parties’ only disagreement is how to measure the width.

Ethicon contends that the width of the clamping surface area is measured using the entire width of the tissue pad and includes both where the blade and tissue pad are in direct contact and where the blade and tissue are in close proximity. (ESUF ¶ 104). Covidien, on the other hand, contends that the width of the clamping surface area is

measured using the width of the rounded tip of the Sonicision device. (CSUF at ¶ 127).

The '055 Patent specification defines "clamping surface area" as "the area where the blade and the tissue pad are in close proximity when the clamping arm is in a closed position." ('055 Patent, col. 1:30–56). In its 2015 decision, the Federal Circuit cited the same portion of the '501 Patent specification, which is identical to the '055 Patent, to note that the "specification explains that this 'clamping surface area is the area where the blade and the tissue pad are in close proximity because the arm is in a closed position.'" *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1317 (Fed. Cir. 2015) (quoting the '501 Patent).

Covidien points to the Federal Circuit language that the clamping surface area is "defined by the tissue pad and the blade." *Id.* Covidien uses this language to argue that the teachings of the '055 Patent and the Federal Circuit's decision support its position that "the clamping surface area of the Sonicision device must be defined by the contact area between the blade's rounded tip and the tissue pad, when the clamping arm is in the closed position." (Doc. 189 at 36). However, accepting Covidien's preferred definition of clamping surface area would interpret the "close proximity" language out of the '055 Patent entirely. For that reason, the Court finds that the teachings of the '055 Patent and the Federal Circuit's decision make clear that the clamping surface area is "defined by the tissue pad and the blade" where the blade and the tissue pad are in close proximity.

Having found that Ethicon properly interpreted the '055 Patent's teachings on how to calculate the clamping surface area, the Court finds that there are no disputed facts that the Sonicision devices infringe on the clamping pressure range of the '055 Patent. As noted, the only disputed fact was how to measure the width of the clamping surface area. Covidien's expert noted that his only disagreement with Ethicon's expert's measurement of the clamping surface area was the width. (Durfee Tr. at 116:9–23). At his deposition, Dr. Durfee acknowledged that the maximum width of the Sonicision blade is wider than the tissue pad. (Durfee Tr. at 142:21–25). Indeed, Dr. Durfee recognized that Sonicision's blade and tissue pad are in close proximity for the entire tissue pad, not just the rounded tip. (*See id.* at 136:3–9). Thus, Dr. Durfee should have measured the clamping surface area of the Sonicision device by using the width of the entire tissue pad. Because Dr. Durfee's calculation of clamping surface area was based on an improper interpretation of the '055 Patent, his calculation of clamping pressure is inaccurate.

Mr. Leinsing, Ethicon's expert, used the proper methodology to calculate clamping surface area, defined by where the blade and the tissue pad are in close proximity. Mr. Leinsing's calculations of the clamping surface area of the Sonicision device are shown in the table below

Sonicision Product No.	Active Pad Length (in.)	Pad Width (in.)	Clamping Surface Area (in^2)
SON-13-1	0.599	0.050	0.029950
SON-13-2	0.600	0.051	0.030600
SON-13-3	0.600	0.051	0.030600
SON-26-1	0.600	0.050	0.030000

Sonicision Product No.	Active Pad Length (in.)	Pad Width (in.)	Clamping Surface Area (in^2)
SON-26-2	0.600	0.051	0.030600
SON-26-3	0.599	0.051	0.030549
SON-39-1	0.601	0.051	0.030651
SON-39-2	0.600	0.050	0.030000
SON-39-3	0.600	0.051	0.030600
SON-48-1	0.602	0.051	0.030702
SON-48-2	0.600	0.051	0.030600
SON-48-3	0.600	0.051	0.030600

(Doc. 186-7 ("Leinsing Report") at ¶ 49)

Mr. Leinsing then used his accurate calculation of the Sonicision devices' clamping surface area to calculate the Sonicision devices' clamping pressure. He found that the Sonicision devices exert clamping pressures in the 120 to 210 psi pressure range; this range is within the clamping pressure limitation of the '055 Patent. The clamping pressure calculations are shown in the table below.

Sonicision Product No.	Clamping Force (measured) (lbs.)	Clamping Pressure (calculated using the measured clamping force) (lbs./in^2, psi)
SON-13-1	5.1	168.95
SON-13-2	4.8	158.41
SON-13-3	5.2	171.02
SON-26-1	4.6	154.69
SON-26-2	5.1	167.91
SON-26-3	5.0	162.34
SON-39-1	4.4	142.16
SON-39-2	4.5	150.05
SON-39-3	4.6	151.58
SON-48-1	4.8	154.83
SON-48-2	4.7	153.70
SON-48-3	4.0	132.16

(Leinsing Report at ¶ 59)

This clamping pressure range for the Sonicision device infringes on the '055 Patent. Accordingly, the Court finds that Ethicon has shown that there is no genuine issue of material fact that the Sonicision devices infringe on claims 9, 10, and 20–25 of the '055 Patent.

Therefore, Ethicon's motion for summary judgment of infringement (Doc. 186) is **GRANTED** and Covidien's motion for summary judgment of noninfringement (Doc. 188) is **DENIED in part** to the extent that Covidien claims the Sonicision device does not infringe on any of the '055 Patent's claims because the Sonicision device exerts clamping pressure outside of the claimed 120 to 210 psi pressure range.

b. Infringement by Sonicision – Predetermined Force (Claims 1, 2, 4, 5, 8, and 14)

Covidien moves for summary judgment of noninfringement of claims 1, 2, 4, 5, 8, and 14 of the '055 Patent on the grounds that the Sonicision device does not practice the "predetermined" limitation. Covidien notes that the Court, during the '501 Patent litigation, determined that the Sonicision device did not infringe the '501 Patent because the clamping force that the Sonicision device exerts is not predetermined. (Doc. 131 at 42–44). Covidien argues that because Ethicon did not appeal that noninfringement determination (*see Ethicon*, 796 F.3d at 1314–15) to the Federal Circuit, the Court's decision regarding noninfringement due to failure to satisfy the "predetermined" limitation is controlling. *See Del Mar Avion, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987) ("The prior determination of certain issues, including the

issues of claim construction and of infringement by the type A and non-infringement by the type C models, bars judicial redetermination of those issues as between the parties to the prior actions.").

To invoke issue preclusion a party must establish four preconditions: "(1) identity of the issues in a prior proceeding; (2) actual litigation of those issues; (3) necessity of the prior determination to the resulting judgment; and (4) full and fair opportunities to litigate issues for the party defending against preclusion." *Sacramento Mun. Util. Dist. v. United States*, 566 F. App'x 985, 993–94 (Fed. Cir. 2014). Covidien argues that all preconditions are met here because the same construction of the term "predetermined" is before the Court as was during the litigation of the '501 Patent and the same structures of the Sonicision devices that were accused of infringing the '501 Patent are accused of infringing the '055 Patent. (Doc. 189 at 40).

Ethicon argues that issue preclusion does not apply because this Court's '501 patent noninfringement determination was effectively overturned by the Federal Circuit. Issue preclusion "should not be applied to foreclose full consideration of an issue when there has been a significant change in decisional law between the first case and the second." *Sacramento Mun. Util. Dist. V. United States*, 566 Fed. App'x 985, 994 (Fed. Cir. 2014). The Court has already rejected Ethicon's similar argument in finding that the Federal Circuit's ruling did not have any impact on this Court's previous term construction related to the "predetermined" limitation in the Order on Claim

Construction. (Doc. 176 at 10–12).

The Court agrees with Covidien that all of the preconditions of collateral estoppel are met here. Moreover, consistent with its earlier Order (Doc. 131 at 42–44), the Court finds that the Sonicision device does not exert a "predetermined" force. In order to exert a predetermined force, a device must be set to a value within the claimed pressure range, independent of user control. While the minimum and maximum range of the pressure is determined before the Sonicision device is used, (Durfee Tr. At 181:25-182:21), the clamp force for the Sonicision device varies depending on how hard the surgeon squeezes.

The Court finds that the Sonicision device does not practice the "predetermined" limitation set forth in claims 1, 2, 4, 5, 8, and 14 of the '055 Patent. Accordingly, Covidien's motion for summary judgment of noninfringement (Doc. 188) is **GRANTED in part** to the extent that the Sonicision device does not infringe on claims 1, 2, 4, 5, 8, and 14 of the '055 Patent.

B. Validity of '055 Patent

Next, Covidien moves for summary judgment of invalidity of the '055 Patent. (Doc. 189 at 29–33). Significantly, the '055 Patent is presumed valid. 35 U.S.C § 282. Covidien argues that the '055 Patent is invalid for failing to comply with the written description requirement (35 U.S.C. § 112) and for obviousness (35 U.S.C. § 103(a)).

1. Written Description

The specification of a patent "shall contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112 ¶ 1. "A party must prove invalidity for lack of written description by clear and convincing evidence." *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015). "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party." *PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001)

"[T]he hallmark of written description is disclosure." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). *Id.* The standard for satisfying the written description requirement is whether the disclosure "allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). To determine whether the written description requirement is met, the Court must consider "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."

Ariad, 598 F.3d at 1351. This test "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.*

a. The Messerly Patent is incorporated by reference in the '055 Patent

It is undisputed that the '055 Patent specification describes an ultrasonic surgical shears that includes a spring. (ESUF at ¶ 436). However, Covidien argues that the '055 Patent does not disclose any spring for "limiting force" (claims 1, 2, 4, 5, 8–10, 14, 20–23) or "transferring force" (claims 24, 25) and is therefore invalid for lack of written description. Ethicon contends that the Messerly Patent ('811 Patent),[5] which discloses the claimed springs for limiting a clamping force, is part of the disclosure of the '055 Patent and thus provides adequate written description. The Court agrees with Ethicon.

The Messerly Patent was prior art to the '055 Patent. (CSUF ¶¶ 74–75). The '055 Patent specification provides: "Exemplary devices are described in U.S. Pat. Nos. 5,322,055 and [the Messerly Patent], the contents of which are incorporated herein by reference." ('055 Patent at col. 1:41–43). Covidien and Covidien's expert have both recognized that the Messerly Patent is incorporated into the disclosure of the '055 Patent in its entirety. (ESUF ¶¶ 314–15, 326). Thus, the Court finds that it is undisputed that

[5] Ethicon patent, U.S. Patent No. 6,325,811 to Messerly (the "Messerly Patent" or the "'811 Patent), was filed on October 5, 1999 and is prior art to the '055 Patent. (CSUF ¶¶ 74–75).

the Messerly Patent was incorporated by reference in the '055 Patent specification. *See X2Y Attenuators, LLC v. ITC*, 757 F.3d 1358, 1362–63 (Fed. Circ. 2011) (when a patent is incorporated by reference, "[t]he incorporated patents are 'effectively part of the host [patents] as if [they] were explicitly contained therein.'") (quoting *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001)).

b. Spring for limiting force/transferring force

Covidien concedes that the Messerly Patent discloses a force limiting spring, (Doc. 191-14 at col. 7:55–8:29), and a spring for transferring force. (*Id.* at 7:61–63). Covidien's expert also recognizes that the Messerly Patent includes a "force-limiting spring" and "force-transferring spring." (ESUF ¶¶ 354, 359). Yet Covidien argues that the '055 Patent specification, on its face, does not teach one of ordinary skill to employ the Messerly Patent as a force limiting or force transferring spring, but instead describes Messerly in connection with a spring creating force.

Covidien cites the Federal Circuit's decision in *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) in arguing that Ethicon cannot properly rely on the Messerly Patent's incorporation by reference into the '055 Patent. *Id.* at 1160 ("the district court properly rejected [expert's] reliance on an incorporation by reference of a [prior art] patent" to satisfy written description requirement). Yet the facts in *Tronzo* are easily distinguished from those currently before the Court.

In *Tronzo*, the Federal Circuit denied a foreign patentee the priority date from its

parent application. *Id*. at 1159. The patent at issue in that case related to artificial hip sockets including cup implants adapted for insertion into a hip bone. *Id.* at 1156. The parent application had described only conical cups, while the later United States patent application disclosed hemispherical cups. The patent holder argued that the foreign patent application had described a number of cups, thus generically claiming hemispherical cups. *Id.* The Federal Circuit rejected this argument because the parent application emphasized that the conical shape was "extremely important," and only referenced non-conical cups to distinguish the conical cups as superior. *Id.* Because of this, the Federal Circuit found that the foreign application contained no reference to the later-claimed hemispherical cups and limited the earlier invention to conical cups.

Notably, in *Tronzo* the only mention of non-conical shaped cups was to emphasize that conical shaped cups were superior to prior art. Here, if the Messerly Patent had disclosed that springs for limiting / transferring clamping force would be inferior to other springs, and then Ethicon tried to rely on that language to argue that the '055 Patent disclosed springs for limiting / transferring force by incorporating the Messerly Patent, *Tronzo* would be informative. However, Ethicon contends that the '055 Patent provides adequate written description of a spring for limiting / transferring force because the Messerly Patent, which was incorporated into the '055 Patent, clearly describes the use of springs for limiting and transferring clamping force.

The Court finds that the Messerly Patent discloses both a spring to limit a

clamping force and a spring to transfer a clamping force. The Court also finds that the Messerly Patent is broadly and unequivocally incorporated into the disclosure of the '055 Patent in its entirety. Accordingly, the Court finds that '055 Patent specification discloses a spring that limits force and a spring that transfers force and complies with the written description requirement of 35 U.S.C. § 112.

Moreover, in its Order on Claim Construction, the Court found that the ordinary meaning of "the term 'spring' is apparent, and the inventor did not specifically define the term or disavow its customary meaning." Similarly, the Court finds that a reasonable juror could find that one of ordinary skill in the art would understand that springs both limit and transfer force.

The Court cannot find that Covidien has provided such clear and convincing evidence of invalidity of the '055 Patent for lack of written description that no reasonable juror could find otherwise. Accordingly, Covidien's motion for summary judgment that the '055 Patent is invalid for lack of written description is **DENIED**.

2. Obviousness

Obviousness is a question of law based on underlying facts. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356–57 (Fed. Cir. 2012). "To prevail on obviousness, an alleged infringer must prove by clear and convincing evidence 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a

reasonable expectation of success in doing so." *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). In conducting an obviousness analysis, a court "must guard against 'hindsight bias' and 'ex post reasoning.'" *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013).

Secondary considerations or objective indicia of non-obviousness are important in an obviousness analysis. *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016). Secondary considerations serve to guard against hindsight bias. *Id.* Secondary considerations include: "commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention." In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), the Federal Circuit held:

> Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Id. at 1538.

Covidien contends that all claims of the '055 Patent are obvious because the only claim Ethicon contends to be missing from the prior art – the higher clamping pressure of 120 to 210 psi – is insufficient to confer patentability over prior art. Where the difference between a claimed invention and prior art is a range within the claims "the applicant must show that the particular range is critical, generally by showing that the claimed range

achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Covidien argues that there is no genuine issue of material fact that: (1) a person of ordinary skill in the art would be motivated to apply higher pressures in the claimed 120 to 210 psi range with a reasonable expectation of success; (2) the 120 to 210 psi clamping pressure range is not critical to vessel sealing with ultrasonic surgical instruments, including on 5mm blood vessels up; and (3) the inventor's experiments with clamping pressures in the 120 to 210 psi range did produce not produce unexpected results as of February 2004. (Doc 189 at 29). Contrarily, Ethicon argues that Covidien's obviousness analysis is tainted with improper hindsight and ignores undisputed evidence.

Ultimately, the Court finds that, while Covidien raises several issues of fact indicating that the '055 Patent may be invalid for obviousness, Covidien has not shown obviousness by clear and convincing evidence. Ethicon points to several material facts such that a reasonable juror could find that the '055 Patent was non-obvious. (Doc. 201 at 16–25).

First, Ethicon provides evidence to support its contention that a person of ordinary skill in the art at the time of the invention would not have been motivated to combine the teachings of the cited prior art to apply a clamping pressure in the claimed range, including: Dr. Durfee testified that it was known in February of 2004 that increasing clamping pressure could have poor effect on vessel sealing (Durfee Tr. at 219:21–

220:18); and a book published in 2005 ("Feil") includes a chapter entitled "Principles of Ultrasonic Energy for Cutting and Coagulating" that includes the figure below that associates "faster cutting" with "less hemostasis" and "slower cutting" with "more hemostasis."

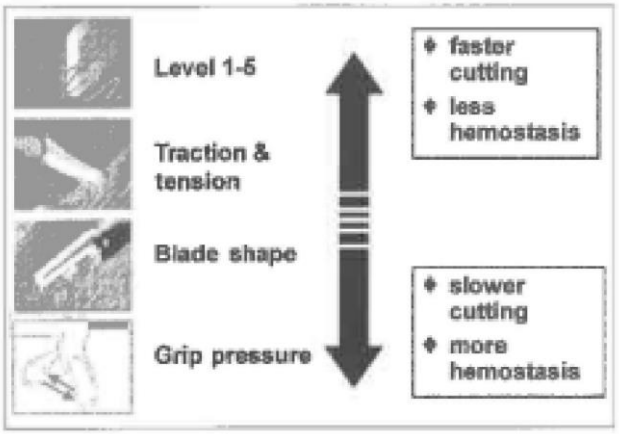


Fig. 2.21 Practical use of the UltraCision shears. The balance between cutting and coagulation can be controlled by changing the level, applying more or less tension and traction, selecting a special blade or blade side, or applying more or less grip pressure.

(*See* ESUF at ¶¶ 365–66). Both of these facts cast doubt on the proposition that a person of ordinary skill in the art would be motivated to apply higher clamping pressures with a reasonable expectation of success. Ethicon also raises issues on whether U.S. Patent Application No. 2003/0055417, "Surgical System for Applying Ultrasonic Energy to Tissue" ("Truckai"), relied upon by Covidien for the proposition that "one of ordinary skill in the art at the time of the invention would have naturally been motivated to apply higher pressures to prior art" (Doc. 189 at 29–30), actually teaches away from pursuing higher forces and pressures found in the '055 Patent. (*See* Doc. 201 at 18–21). Overall,

the Court finds that Ethicon has raised issues of material fact on whether a person of ordinary skill in the art would be motivated to apply higher pressures in the claimed 120 to 210 psi range with a reasonable expectation of success.

Second, to dispute that the '055 Patent's claimed pressure range of 120 to 210 psi is not critical, Ethicon cites to the testimony of the inventor of the '055 Patent and Mr. Leinsing that that pressure in the 120 to 210 psi range performed better than pressures in the 60 to 119 range. (Doc. 201-12 ("Houser Tr.") at 941:3–8; Doc. 201-13 ("Leinsing Tr.") at 139:10–23). This testimony indicates that there is a genuine issue of material fact of whether the pressure range of 120 to 210 psi provides optimal performance or is critical, which would render the '055 Patent non-obvious.

Third, while Covidien's argument that 120 to 210 psi range was not critical because it was found through "trial and error" (CSUF ¶ 220) has some merit, *see K-Swiss, Inc. v. Glide N Lock GmbH*, 567 F. App'x 906, 913 (Fed. Cir. 2014) ("'where the general conditions of a claim are disclosed in prior art,' as here, 'it is not inventive to discover the optimum range by routine experimentation.") (citing *In re Aller*, 42 C.C.P.A. 824, 220 F.2d 454, 456 (1955)), Ethicon argues that this is impermissible hindsight. The Federal Circuit has found that "the inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017). Ethicon cites the

testimony of the ‘055 Patent inventor to support its claim that there was no reasonable expectation of success in increasing the clamping force of the prior art devices in order to arrive at the claimed invention. (Houser Tr. at 59:3–20, 702:16–704:21, 724:14-726:25). Covidien has not shown by clear and convincing evidence that the higher clamping pressure range did not produce unexpected results.

Finally, even if Covidien has established a *prima facie* case of obviousness of the ‘055 Patent, the objective evidence indicates that there are genuine disputes of material fact related to obviousness. Ethicon points to several objective indicia of non-obviousness that preclude invalidating the ‘055 Patent as obvious, including the commercial success of Ethicon’s ultrasonic devices and praise within the industry. Ethicon highlights that its Harmonic ACE, an ultrasonic surgical device that embodies the claimed invention, was recognized by the Ultrasonic Industry Association as the Best New Ultrasound Product for 2005. (ESUF ¶¶ 231, 410). *See Apple Inc.*, 839 F.3d at 1053 (“Evidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion that the same claimed invention would have been obvious. Industry participants, especially competitors, are not likely to praise an obvious advance over the known art. Thus, if there is evidence of industry praise of the claimed invention in the record, it weighs in favor of the non-obviousness of the claimed invention”). Although Ethicon’s reply brief presents issues of whether the publication that praised Ethicon’s device represents an independent, third-party analysis (Doc. 208 at

12), that is an issue of disputed fact.

The Court finds that Covidien has failed to show obviousness of the '055 Patent by the clear and convincing evidence required to overcome the presumption of validity. Therefore, Covidien's motion for summary judgment on the grounds that the '055 Patent is invalid for obviousness is **DENIED**.

V. NON-INFRINGING ALTERNATIVES ANALYSIS (Docs. 184, 192)

Having found that Covidien's Sonicision device infringes on claims 9, 10, and 20–25 of Ethicon's '055 Patent, the Court now turns to the parties' motions relating to damages. Ethicon moves for summary judgment on absence of acceptable and available non-infringing alternatives. (Doc. 184). Covidien, on the other hand, moves for partial summary judgment precluding lost profit damages because it contends that non-infringing alternatives were available. (Doc. 192).

Upon proof of infringement, 35 U.S.C. § 284 provides that a "court shall award [the patent owner] damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer." The phrase "damages adequate to compensate" means "full compensation for 'any damages' [the patent owner] suffered as a result of the infringement." *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 657 (1983); *Grain Processing Corp. v. American Maize–Prods.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). Damage awards fall within two general categories, to wit: (1) actual damages, *e.g.*, lost profits, and (2) when actual damages

cannot be established, a reasonable royalty. An award of damages may be split among both categories if necessary to compensate the patent owner fully. *See State Indus., Inc. v. Mor–Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989).

To establish entitlement to lost profits, "the patent owner has an initial burden to show a reasonable probability that he would have made the asserted sales 'but for' the infringement." *Grain Processing*, 185 F.3d at 1349. To meet this burden, a patent owner generally must prove four factors set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978): (1) demand for the patented products; (2) absence of acceptable non-infringing alternatives; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made. *Id.* at 1156.

Here, Ethicon's motion does not seek summary judgment with respect to lost profits generally, but instead seeks summary judgment on the second *Panduit* factor, contending that Covidien's alleged non-infringing alternatives were neither acceptable nor available. Covidien's motion also focuses on the second *Panduit* factor, contending that Ethicon is not entitled to recover lost profits damages because acceptable non-infringing alternatives were available.

"[A] noninfringing alternative need not be on the market during the infringement period to factor into a lost profits analysis." *Wechsler v. Macke Intern. Trade, Inc.*, 486 F.3d 1286, 1298 (Fed. Cir. 2007). However, where an alleged non-infringing alternative was not on the market during the relevant time period, "a trial court may

reasonably infer that it was not available as a non-infringing substitute at that time. The accused infringer then has the burden to overcome this inference by showing that the substitute was available." *Grain Processing*, 185 F.3d at 1353 (citation omitted). Moreover, "[t]he acceptable substitute element, though it is to be considered, must be viewed with limited influence where infringer knowingly made and sold the patented product *for years while ignoring the substitute*." *Panduit*, 575 F.2d at 1162, n,9.,

Covidien does not dispute that its alleged non-infringing alternatives were not on the market during the relevant time period. Therefore, Covidien bears the burden to overcome the inference of non-availability. *See Grain Processing*, 185 F.3d at 1353.

Having "the necessary equipment, know-how, and experience" to make an alternative product during the relevant time may render the product "available." *Id.* at 1354–55. However, the "high cost of a necessary material" or a "finding that an infringer had to design or invent around the patented technology to develop an alleged substitute weighs against a finding of availability." *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1123 (Fed. Cir. 2003). "'Mere speculation or conclusory assertions will not suffice to overcome the inference' that posited non-infringing alternatives that were not on the market nevertheless were available during the relevant period of alleged infringement." *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 117 (quoting *Grain Processing*, 185 F.3d at 1353). "[T]he trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement." *Grain*

Processing, 185 F. 3d at 1353.

Here, Covidien contends that at least two non-infringing alternatives to its infringing Sonicision device were available during the relevant time period: (1) a device that shortens the coil spring to apply pressures outside of the 120 to 210 psi claimed range ("shortening the force spring"); and (2) a device that replaces the coil spring with a rigid member ("replacing the spring"). (Doc. 193 at 19).

While both parties have raised issues of material fact in dispute regarding the acceptability of the posited non-infringing alternatives,[6] the Court finds on the material, undisputed facts that Covidien has failed to meet its burden to overcome the inference of non-availability.

Covidien correctly relies on *Grain Processing* for the notion that an alternative device need not be on the market to be available as long as the infringer has the necessary equipment, know-how, and experience to make the alternative product at the time of the infringement. In *Grain Processing*, however, a device was found to be available when "it took only two weeks to perfect [the alternative] and begin mass producing" the product. *Grain Processing,* 185 F.3d at 1346. Yet in *Micro Chem,* the Federal Circuit found that a device was not available at the time of infringement when it took over four months to convert infringing devices into non-infringing devices. *Micro Chem.*, 318 F.3d at 1123.

[6] For example, the Court finds that facts in the record are in dispute over whether Covidien's proposed alternative devices would be acceptable to consumers and comparable to the Sonicision devices on the market, and whether clamping pressures outside the '055 Patent range are as effective. (Doc. 193 at 17–20; Doc. 184 at 19–21).

The Federal Circuit held that an alleged non-infringing alternative is unavailable where the record shows that the infringer "designed around the patented technology" after infringement was established. *Id.*

The record in this case clearly shows that it would take between 46 and 62 weeks. (EDSUF at ¶ 28). Regarding the amount of time, cost, and work that would be required to design around the '055 Patent, Covidien's expert Dr. Keith Ugone stated:

> Based upon a discussion with Covidien personnel, Covidien could have designed around the '055 Patent at a modest cost and within a reasonable time period.
>
> a. Changing the force spring. According to Mr. Jason Craig, Covidien would need 12 weeks to design and build three to four proto-type molds and test the tooling. This process would require an estimated $105,000 in labor and $5,000 in tools and materials expenses. After the testing, Covidien would need about 34 weeks to build additional tooling for large scale production; test, validate, and qualify the tooling; and file and obtain the appropriate approvals from a corresponding 510K submission. This implementation step would cost $280,000. In total, it would have taken Covidien an estimated 46 weeks and $390,000 to design around the '055 Patent using this design.
>
> b. Replacing the spring. Covidien could replace the spring with a rigid member. Covidien would need 24 weeks to design and build three to four proto-type molds and test the tooling. This process would require an estimated $250,000 (i.e., $40,000 in tools and materials expenses and $210,000 in labor costs). After the testing, Covidien would need about 38 weeks to build additional tooling for large scale production; test, validate, and qualify the tooling; and file and obtain the appropriate approvals from a corresponding 510K submission. This implementation step would cost $425,000 (i.e., $100,000 for tools and materials and $325,000 for manpower). In total, it would have taken

> Covidien an estimated 62 weeks and $675,000 to design around the ‘055 Patent using this design.

(Doc. 184-10 at ¶ 120).

Thus, it is undisputed, based on Covidien’s own estimates, that it would have taken over 10 months to design around the ‘055 patent—well over twice the time required to produce an alternative (which was deemed unavailable) in *Micro Chem*. The Court finds that this clearly shows that Covidien’s posited non-infringing alternatives were unavailable at the time of infringement. Covidien has not come close to overcome the inference of non-availability, therefore the alleged non-infringing alternative devices were not available as a matter of law.

Accordingly, Ethicon’s motion for summary judgment of absence of acceptable and available non-infringing alternatives (Doc. 184) is **GRANTED** and Covidien’s motion for summary judgment precluding lost profits damages (Doc. 192) is **DENIED**.

VI. CONCLUSION

Accordingly, for the foregoing reasons:

1) Ethicon’s motion for summary judgment of infringement of claims 9, 10, and 20–25 (Doc. 186) is **GRANTED**.

2) Covidien’s motion for summary judgment (Doc.188) is **GRANTED in part** and **DENIED in part** as follows:

    a. Covidien’s motion for summary judgment of invalidity is **DENIED**;

    b. Covidien’s motion for summary judgment of noninfringement of claims 1, 2, 4, 5, 8, and 14 of the ‘055 Patent is **GRANTED**;

c. Covidien's motion for summary judgment of noninfringement of all other claims is **DENIED**.

3) Ethicon's motion for summary judgment of absence of acceptable and available non-infringing alternatives (Doc. 184) is **GRANTED**.

4) Covidien's motion for summary judgment precluding lost profits damages (Doc. 192) is **DENIED**.

IT IS SO ORDERED.

Date: 5/16/19

Timothy S. Black
United States District Judge