UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORPORATION, *Plaintiffs*, *v.* ETHICON ENDO–SURGERY, INC., *Defendant*.	Civil No. 3:10cv60(JBA) March 28, 2013

MEMORANDUM OF DECISION

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I. Summary of Findings and Conclusions

A bench trial was held from December 3 through December 13, 2007, and July 9 through August 3, 2012[1] on the claims of Plaintiffs Tyco Healthcare Group LP and United States Surgical Corporation ("Tyco") that Defendant Ethicon Endo–Surgery, Inc.'s

[1] The second phase of the trial was also held in two parts: July 9–July 13, 2012 and July 23–July 27, 2012, with closing arguments heard on August 3, 2012.

("Ethicon") ultrasonic surgical tools infringe three patents,[2] and on Defendant's invalidity defenses. The Court's findings and conclusions pursuant to Federal Rule of Civil Procedure 52 are summarized as follows:[3]

(1) Tyco has proved infringement of all asserted claims of the patents in suit;

(2) Ethicon has proved its defense of prior conception and diligence under § 102(g) for claims 1, 5, 9, and 10 of the '050 patent, claims 1, 6, 7, and 8–14 of the '286 patent, and 1, 2, 9–13, 16, 18, and 23–25 of the '544 patent;

(3) Ethicon has failed to prove its § 103 obviousness defense;

(4) Tyco has not proved willful infringement of the patents in suit;

(5) Tyco has not proved that a preliminary injunction is warranted;

(6) Tyco has not proved that it is entitled to lost profits damages; and

(7) Tyco is entitled to 8% royalty damages and 3.25% prejudgment interest for damages in the total amount of $176,500,800.00.

II. Background

A. Overview of Patented Technology

The three patents at issue in this lawsuit are directed to ultrasonic surgical devices, which employ ultrasonic energy to cut and coagulate vessels in surgery. An ultrasonic medical device of the type in the patents in suit is described as including (1) a generator

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[2] The patents in suit are U.S. Patent No. 6,063,050 (the '050 patent), U.S. Patent No. 6,468,286 (the '286 patent), and U.S. Patent No. 6,682,544 (the '544 patent).

[3] Technically still pending, Tyco's oral motions for judgment as a matter of law pursuant to Rule 50(a) [Doc. ## 197, 201] and Ethicon's oral motions for judgment as a matter of law pursuant to Rule 50(a) [Doc. ## 196, 202] are denied. The substance of those motions is addressed in this memorandum of decision. For the reasons set out *infra*, Ethicon's motion to strike testimony of Dr. Durfee [Doc. ## 203, 212] is also denied.

to power a transducer, (2) a transducer to convert electrical energy into ultrasonic mechanical vibrations, and (3) the surgical instrument to deliver ultrasonic energy to tissue. (*See* Fig. 1, '286 patent [PTX 52].) Ultrasonic energy vibrates a blade at the end of the instrument very rapidly such that the device cuts tissue and provides hemostasis through the generation of frictional heating between the tool and tissue. (*See, e.g.*, Fig. 12, '050 patent [PTX 50].)

The ultrasonic transducer (*see id.* at 230) is supported within the instrument's housing. The shaft (*id.* at 224) and the jaw (*id.* at 232) can be rotated by a rotation knob (*id.* at 234). The devices at issue are commonly used in laparoscopic surgery in which trocars are used to pierce a patient's body and a narrow hollow tube, or "cannula," is used to provide a "working pathway" to the target surgical site. (*See* Expert Report of William Cimino [DTX 1379] ¶¶ 9–10.) The incisions created in laparoscopic surgery are relatively small and the result is shorter hospital stays and periods of convalescence, as well as less post–operative pain and fewer wound complications than in traditional, open surgery. (*See id.* ¶ 10.)

The patented technology describes handles that can be used to open and close the clamp jaw. (*See* stationary handle (228) and movable handle (236), Fig. 25, '050 patent.) In one embodiment, the clamp jaw is closed by pulling the movable handle towards the stationary handle ('050 patent at 11:1–9). When the movable handle moves towards the stationary handle, a cam mechanism advances the actuator tube toward the working end of the instrument. (Fig. 24, '050 patent.)

The three patents in suit are similar, but the '050 patent, part of the "Manna" family of patents discloses a cutting jaw with an "angled" blade surface ('050 patent at 1:60–67), while the '286 and '544 patents disclose a cutting jaw "curved downwardly and

outwardly in the distal direction" ('286 patent at 1:65–67; '544 patent [PTX 53] at 1:67–2:2; *see also* Fig. 19, '050 patent; Fig. 9, '286 patent.)

B. Accused Instruments

Tyco asserts that the Ethicon's Harmonic Scalpel products, Harmonic ACE products, and Harmonic WAVE products, all ultrasonic cutting and coagulating surgical devices used in laparoscopic and open surgery procedures, infringe claims 10–12 of the'050 patent, claims 8–14 of the '286 patent, and claims 1–3, 6, 8–13, 16, 18, and 23–25 of the '544 patent. Specifically, Tyco contends that the following Ethicon devices infringe the patents in suit:

"CS Products"	CS141 CS14C CS231 CS23C
"LCS Products"	LCSC1 LCSC5 LSCS5L
"ACE Products"	ACE14S ACE23S ACS36S ACE23P ACE36P ACE23E ACE36E ACE45E
"Wave Products"	WAVE18S

Tyco asserts that the LSC, CS, and ACE products infringe claims of the '050, '286, and '544 patents, and that the Wave Products infringe claims of the '544 patent. In the Court's 2007 Ruling on Motions for Summary Judgment, *Tyco Healthcare Group LP v.*

Ethicon Endo–Surgery, Inc., 514 F. Supp. 2d 351 (D. Conn. 2007), the LSC, CS, and ACE products were found to infringe claims 1, 5, and 9 of the '050 patent and claims 1, 6, 7 and 15 of the '286 patent.[4]

C. The Asserted Claims of the Patents In Suit

This chart summarizes Tyco's infringement claims against the accused devices. An indication of "infringed" in the far–right column means that the Court, in its 2007 Ruling on Motions for Summary Judgment, found that the accused products infringe those claims:

Patent	**Claim**	**LCS, CS, and ACE Products**	**WAVE**	**Elements Contested**
'050	1	X		Infringed
	5	X		Infringed
	9	X		Infringed
	10	X		Sealing Ring
	11	X		Camming
	12	X		Camming
'286	1	X		Infringed
	6	X		Infringed
	7	X		Infringed
	8	X		Camming
	9	X		Camming
	10	X		Camming, Coupling Member
	11	X		Camming, Coupling Member, Swivel Member

[4] Ethicon has stipulated that the Court's 2007 Summary Judgment Ruling is also applicable to the newly accused ACE products—that is, the ACE23E, ACE36E, and ACE 45E. (*See* Stipulation [Doc. # 59].)

	12	X		Camming, Coupling Member, Swivel Member
	13	X		Camming, Coupling Member, Swivel Member
	14	X		Camming
	15	X		Infringed
'544	1	X	X	Camming
	2	X	X	Camming
	3	X	X	Camming
	6	X		Camming
	8	X		Camming, Curved Surface, Longitudinally Extending
	9	X	X	Camming
	10	X		Camming
	11	X		Camming
	12	X		Camming
	13	X	X	Camming
	16	X	X	Camming
	18	X		Camming
	23	X		Camming
	24	X		Camming
	25	X	X	Camming

The remaining claims of the '050 patent at issue are:

> Claim 10: The surgical instrument of claim 1, further comprising at least one ring positioned on the vibration coupler to seal the flow of fluids between the vibration coupler and the actuator tube.
>
> Claim 11: The surgical instrument of claim 1, wherein the clamp member includes a pair of pivot pins and a pair of camming members spaced from the pivot pins.

> Claim 12: The surgical instrument of Claim 1, wherein the actuator tube includes a pair of slots engagable with a pair of camming members of the clamp member.

('050 patent.)

The remaining claims of the '286 patent that Tyco asserts are infringed by Ethicon's products are:

> Claim 8: An ultrasonic instrument according to claim 7, further including an actuator tube slidably positioned about the vibration coupler, a distal end of the actuator tube including a cam slot configured to receive cam members formed on the clamp member, the actuator tube being moveable between advanced and retracted positions about the vibration coupler in response to actuation of the handle assembly to effect movement of the clamp member between the open and closed positions.
>
> Claim 9: An ultrasonic instrument according to claim 8, wherein the handle assembly includes a stationary handle and a moveable handle, the movable handle being operably connected to a proximal end of the actuator tube.
>
> Claim 10: An ultrasonic instrument according to claim 9, further including a coupling member, the coupling member interconnecting the actuator tube and the moveable handle.
>
> Claim 11: An ultrasonic instrument according to claim 10, wherein the coupling member includes a swivel member, the swivel member being positioned to permit rotation of the coupling member in relation to the moveable handle.
>
> Claim 12: An ultrasonic instrument according to claim 11, wherein the coupling member is operably connected to a rotatable knob positioned adjacent the handle assembly, the rotatable knob being rotatably secured to the handle assembly such that rotation of the rotatable knob in relation to the handle assembly effects corresponding rotation of the coupling member and the clamp member.
>
> Claim 13: An ultrasonic instrument according to claim 12, wherein the vibration coupler is rotatably fixed to the rotatable knob such that rotation of the rotatable knob in relation to the handle assembly effects corresponding rotation of the vibration coupler and the cutting jaw.

> Claim 14: An ultrasonic instrument according to claim 8, further including an outer tube positioned about the actuator tube, the clamp member being pivotally connected to the outer tube.

('286 patent.)

Tyco also asserts that claims 1–3, 6, 8–13, 16, 18, and 23–25 of the '544 patent are infringed by Ethicon's LSC, CS, ACE, and WAVE products:

> Claim 1: An ultrasonic instrument comprising: an outer tube defining a longitudinal axis and having a proximal end and a distal end; an actuation member positioned within the outer tube; a vibration coupler positioned within the outer tube, the vibration coupler having a distal end and a proximal end; a jaw member extending from the distal end of the vibration coupler; a clamp pivotally mounted adjacent the distal end of the outer tube, the clamp being movable in relation to the jaw member between open and clamped positions, the clamp including a camming member which operatively engages the actuation member such that movement of the actuation member pivots the clamp between the open and clamped positions.
>
> Claim 2: An ultrasonic instrument according to claim 1, wherein the actuation member includes a slot for receiving the camming member of the clamp.
>
> Claim 3: An ultrasonic instrument according to claim 2, wherein the claim includes a pair of camming members and the actuation member includes a pair of slots, each one of the pair of slots being positioned to receive one of the pair of camming members.
>
> Claim 6: An ultrasonic instrument according to claim 1, wherein the jaw member includes a curved blade surface.
>
> Claim 8: An ultrasonic instrument according to claim 6, wherein the curved blade surface includes a longitudinally extending cutting edge.
>
> Claim 9: An ultrasonic instrument according to claim 1, further including a handle assembly, the proximal end of the outer tube being supported adjacent the handle assembly.

> Claim 10: An ultrasonic instrument according to claim 9, further including a rotatable collar operatively associated with the vibration coupler, the clamp and the jaw member such that rotation of the vibration coupler causes corresponding rotation of the clamp and the jaw member.
>
> Claim 11: An ultrasonic instrument according to claim 10, wherein the clamp and the jaw member are rotatable about the longitudinal axis of the outer tube.
>
> Claim 12: An ultrasonic instrument according to claim 10, wherein the rotatable collar is positioned adjacent the handle assembly.
>
> Claim 13: An ultrasonic instrument according to claim 9, further including a transducer removably supported on the handle assembly.
>
> Claim 16: An ultrasonic instrument according to claim 13, wherein the transducer includes a transducer horn adapted to engage a proximal end of the vibration coupler.
>
> Claim 18: An ultrasonic instrument according to claim 1, wherein the outer tube is dimensioned to be received within a 5 mm trocar assembly.
>
> Claim 23: An ultrasonic instrument according to claim 1, wherein the clamp includes at least one tissue receiving stop which is positioned adjacent the jaw member.
>
> Claim 24: An ultrasonic instrument according to claim 23, wherein the jaw member includes a blade surface having a proximal and a distal end, . . . at least one tissue receiving stop being positioned adjacent the proximal end of the blade surface.
>
> Claim 25: An ultrasonic instrument according to claim 1, wherein the clamp is pivotally mounted on the distal end of the outer tube.

('544 patent.)

At trial, the main focus of the parties' infringement dispute was on the camming members and the curved blade surface claims.

D. Claim Construction on Relevant Terms

1. Camming Mechanisms and Cam Slots

Claims 11 and 12 of the '050 patent disclose a pair of "camming members," and claim 8 of the '286 discloses "a cam slot configured to receive cam members." Claim 3 of the '544 patent claims a clamp including "a pair of camming members." The Court construed "cam members" and "camming members" identically as: "the follower parts of the cam mechanism that are imparted motion by the cam slots and whose motion is guided by the cam slots." (Cl. Construction [Doc. # 62] at 10.) The Court construed "slots engagable with a pair of camming members" ('050 Patent, Cl. 12; '544 Patent, Cl. 2–3) and "cam slot" ('286 Patent, Cl. 8) as "openings or grooves that impart motion to and guide the motion of the camming members." (Claim Construction at 11.)

2. Swivel Member (Claim 11 and All Dependent Claims of '286 Patent)

The Court construed the term "swivel member" as "[a] component designed to permit the coupling member to swivel or rotate." (*Id.* at 19.)

3. Curved Blade Surface

Claim 6 of the '544 Patent discloses a "curved blade surface," and dependent claim 8 discloses that that surface includes "a longitudinally extending cutting edge." The Court construed claim 6's "curved blade surface" as a "[b]lade surface that has a deviation from a straight line" (*Id.* at 31), and construed the surface disclosed in claim 8 as "[t]he edge of the blade surface designed for cutting that extends along the lengthwise dimension." (*Id.* at 34.)[5]

[5] At summary judgment, the Court found that the CS, LCS, and ACE products infringe claim 15 of the '286 patent, which claims "[a]n ultrasonic instrument according to claim 7, wherein the cutting surface of the cutting jaw is curved along the longitudinal axis of the instrument." *See Tyco*, 514 F. Supp. 2d at 374.

III. Infringement

A. Findings of Fact on Accused Products and Asserted Claims

Tyco's infringement expert Dr. William Durfee testified that he examined each of the accused products and that they infringe all of the asserted patent claims in suit because[6] the accused products each have cam slots and cam members as claimed in each of the asserted patents. Defendant's technical expert Dr. William Cimino challenges the fundamental premise of Dr. Durfee's conclusion—that the mechanism at use in the accused products is a camming mechanism—concluding that it is instead a rack–and–pinion mechanism and thus no claims are infringed by the accused products.

1. Camming

Dr. Durfee defined a "camming mechanism" as:

> A mechanical mechanism that transmits forces and motions through two members, a cam and a follower. And it's through the direct contact of the surface of the cam and the follower that the motions are transmitted back and forth between. Typically, a cam would be the input, and the follower would be the output, so that the cam would give motion to the follower.

(2007 Tr. at 692.) In 2012, Dr. Durfee's analysis continued:

> the first thing you need to determine is whether there is a cam mechanism, and then the second thing you need to determine . . . is in part of that cam mechanism if you've got camming members whose—where motion is imparted to and motion guided by the cam slots. . . . [T]hat's what I used when looking at the accused products in relation to the claim terms of the patents.

(2012 Tr. 293:16–294:1.)

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[6] He initially examined the accused LSC, CS and ACE models products for the 2007 phase of the trial, and then examined the ACE 23E [PTX 603], 36E [PTX 605], 45E [PTX 605], and the WAVE 18S [PTX 606] for this final phase. (2012 Tr. at 284:13–14.)

In considering the clamp on the accused instruments, Dr. Durfee observed that the pivot pin "constrains that clamp to travel in a circle" which he determined to be a "key component" of his opinion that the accused products each possess a camming mechanism as disclosed in the asserted claims of the patents in suit. (*Id* at 295.) Though he conceded that the mechanisms used in the accused products looked different from the drawn images included in the patents, in his opinion, they are, from an engineering standpoint, the same mechanism:

> I want to point out where there's a small difference between the two, if you look on the left, the cam follower, the part 472 [of Fig. 33 of '050 patent] in blue is located above the pivot pin, and if you look on the right on the instrument, it's located below the pivot pin. And so while these two are going to be the same mechanism, that turns out to have a consequence where when they're actuated, in one case you move the tube one way, the other way you move the tube the other way.

(*Id.* at 295:25–296:9.) When asked if that changed his analysis in any way, Dr. Durfee responded, "No, it doesn't. I just wanted to make it clear *it's all the same mechanism, but they might look like they're different because of that choice of where the follower is in relation to the pin.* But it's the same mechanism." (*Id.* at 296:13–17 (emphasis added).)

Dr. Durfee noted that in the '050 patent and in the accused instruments, the tube–in–a–tube design, and the tubes sliding back and forth initiated the process of opening and closing the clamp. (*Id.* at 297.) He described the process in the accused instrument, "as that clamp moves to the right, it takes the protrusion along with it, but that protrusion has to travel in a circle. It's traveling in a circle about its pin, and then in turn it is taking the clamp along with it in a counterclockwise circle as well to close the clamp." (*Id.* at 298:22–299:2.) After discussing how the clamp arm worked, he explained:

> The cam mechanism, it's a mechanism that transfers motion from a cam to a follower through a cam edge or cam surface. Let's take a look at the

> patent. The cam is that slot which is moving left and right, and the follower is the protrusion in blue that is moving in a circle. So the slot—the slot is transferring this motion to the follower through a sliding action on the cam surface, which is the sides of the slot.
>
> The same thing in the photograph of the accused instrument on the right. The cam part of the cam mechanism is the slot and it is transferring its motion to the follower part of the cam mechanism, which is the protrusion. The cam goes back and forth and the follower goes in a circle. So the follower, in order to accommodate that motion, the follower slides against the slot surface. So, again, like the one on the left, the cam surface is the edges of the slot.

(*Id.* at 299:8–300:2.)

Dr. Durfee emphasized that the "angle of the slot . . . in the patent is different than the angle of the slot . . . on the accused product. . . . But that's a particular design choice. . . . that is a choice the designers make, but it doesn't change the fundamental characteristic of this being a cam mechanism." (*Id.* at 300:3–15.) Using the Court's construction that "slots" are "openings or grooves that impart motion to and guide the motion of the camming members," he opined that, as to the accused products, "while that follower can only travel in a circle, its timing of how it gets around the circle is dictated by the slot. . . . So that's the sense that the slots are guiding the motion of the cam members or the followers. (*Id.* at 301:4–11.)

Dr. Cimino disagrees that the accused instruments possess a cam mechanism as disclosed in the patents. Instead, he concluded that in the case of the accused instrument, the "rectangular shaped opening" has a pin used "to engage the actuation member" (*id.* at 847:20), "this is a pin in a slot" (*id.* at 848:21), and testified that "the pin, for intents and purposes, fills the entire slot. I mean, the width of the pin is approximately the width of the slot [so] I do not have any path along which the pin is being guided. I am imparting motion to this pin, but I'm not guiding it down any pathway." (*Id.* at 847:23–848:3.)

Though he agreed that the pin does have a small amount of movement within the slot (*see id.* at 854:4), his opinion was that if one were to change the shape of the "opening" in the accused devices' mechanisms, for example, from a rectangle to a circle, it would have no effect on the motion of the pin, and therefore, "it cannot be a cam" (*id.* at 858:8).

Concluding that it could not be a cam mechanism, Dr. Cimino instead identified the mechanism in the accused products as a "very rudimentary rack and pinion" mechanism (*id.* at 858:22–23), which he defined as "a pulling gear, which is the gear on top that's rotating, and . . . a rack on the bottom. A rack and pinion gear system is really two gears" (*id.* at 859:5–8). On cross–examination, when asked whether "the amount of sliding" between the tooth and the rack "determine[s] whether or not it's a rack and pinion mechanism" (*id.* at 1032:17–19), Dr. Cimino clarified that "[a] rack and pinion is determined by having the elements of a rack and pinion system. So, you would need a rack and a pinned piece to rotate, and they interact through a protrusion or a tooth between the two. That's what would define a rack and pinion mechanism" (*id.* at 1032:20–25).

In response, Dr. Durfee offered a graphic representation of the "single–toothed gear" that Dr. Cimino had identified as a component of a rack and pinion mechanism, but which he defined as a cam mechanism. He demonstrated that by moving the slot to the left and right, "the tooth has pivoted about its axis and has a certain angle" (*id.* at 1777:13–14), emphasizing that "there is a sliding of that tooth on the corner of the . . . slots" (*id.* at 1777:17–18), and "you can clearly see that that transfer of motion is done through the sliding as it is done with the cam" (*id.* at 1777:20–22). Dr. Durfee agreed with Dr. Cimino that if something is "really a cam and I change the cam profile, I'll get a change in the input/output relationship, in other words, a different result" (*id.* at 1778:1–

4), and noted that by changing the cam surface of the slot, "I would need a new equation to describe this cam compared to the previous cam because we've changed the input/output relationship" (*id.* 1779:8–11). Dr. Durfee also testified that a rack and pinion mechanism could be made up of a series of cams, depending on the interaction between the two parts. (*Id.* at 1898.)

When asked about Dr. Cimino's testimony that "if you change the shape of the rectangular slot in the accused devices to a circle it would still operate the same and, therefore, you've changed the profile, you haven't changed the input/output, so therefore you don't have a cam mechanism" (*id.* at 1779:19–25), Dr. Durfee disagreed because:

> [t]he point is when you go from a vertical slot to a circular slot you are going to change the input/output relationship of the cam to the follower. So, you need a new equation to describe the angular excursion of the follower compared to the horizontal version of the cam. So, I would disagree that you are not changing anything about the cam. You are changing the input/output relationship.

(*Id.* at 1780:7–15.) Using Dr. Cimino's slides for his explanation, Dr. Durfee testified that "the amount of sliding does not change whether or not this is a cam mechanism." (*Id.* at 1782:1–2.) Even if the motion of the cam is restricted, "it's still a cam causing transfer motion between the cam and follower. . . it still is a cam that we've got up here no matter how much *or how little sliding there is.*" (*Id.* at 1782:21–23 (emphasis added).) Both experts have testified that there is "sliding contact" between the pin and the slot in the devices, and Dr. Cimino agreed that there is no definite amount of sliding contact that is required for a cam mechanism, as the "amount of sliding in a cam design can vary" (2007 Tr. at 1032:5–6).

Dr. Durfee further testified that Dr. Cimino's reference to the movement of the pin in the rectangular slots of the accused instruments as "mechanical slop" or "mechanical tolerance" was an incorrect characterization, because

> [t]he reason why that pin moves in the slot is because the slot moves in a horizontal motion and the pin moves in a circular motion. So, there has to be sliding between those two for the motions to be compatible. And that's how this cam mechanism is designed. So it's not due to the tolerance of the instrument, it's due to how the components are arranged.

(*Id.* at 1785:7–14.)

The question of whether the mechanism contained in the accused products is a camming mechanism presents a close question that necessitated this trial. The Court finds persuasive Dr. Durfee's explanation of how the mechanisms in the accused products both impart motion and guide along a path, in the same manner that the Court has construed the terms "camming members" and "cam slots" during claim construction. Defendant's evidence does not show absence of movement between the pins and the slots (i.e., the "pin" is not truly "pinned" in the slot, and there is some sliding), nor have they shown that the sliding of the actuator tube does not impart motion and guide the pin within the slot, which in turn results in the opening of the jaws of the clamp members. Both parties' experts agree that the structures used in the WAVE, LCS, CS, and ACE products are the same for purposes of the camming analysis (*id.* at 846), and therefore, the Court finds that all of the accused products possess a cam mechanism as described in the Court's claim construction.

1. The '050 Patent

Dr. Durfee opined that Claim 10 of the '050 Patent, which does not require a cam mechanism or member, is infringed by the accused ACE instruments. His expert report describes claim 10 as requiring "at least one ring positioned on the vibration coupler to

seal the flow of fluids between the vibration coupler and the actuator tube" is satisfied because the "ACE instruments have a series of rings positioned on the vibration coupler. . . . The rings form a tight fit between the vibration coupler and the actuator tube to seal the flow of fluids between the vibration coupler and the actuator tube." (Durfee Report [PTX 538] ¶ 39.) Though he admitted on cross–examination that he had not actually tested the "rings" with liquid to see if they in fact function as sealing rings (*see* 2012 Tr. at 348:1–13), he said that it was unnecessary to form his opinion (*id.* at 348:5). In the 2007 phase, Dr. Durfee did testify about a "test" of sorts "to determine that the sealing ring was tightly fit about the vibration coupler and that the sealing ring tightly fit in the actuator tube." (2007 Tr. at 718.) Defendant offered no evidence disputing his opinion, and the Court finds it more likely than not that the ACE, CS, and LSC instruments meet claim 10 of the '050 patent.

As to remaining claims 11 and 12, since each requires "camming members," and based on his conclusion that the accused products had camming members and cam slots as specified in '050 patent, Dr. Durfee then concluded that these claims are met by the accused products' camming members and cam slots. Dr. Durfee further opined that the pair of pivot pins in the accused products are either two pivot pins or "equivalent of pivot pins" (2012 Tr. at 306:12–13), thus completely satisfying claim 11 of the '050 patent. As to claim 12, Dr. Durfee demonstrated that the accused instrument's actuator tube "includes a pair of slots engagable with a pair of camming members" (*id.* at 308), in support of his opinion that the accused products met all remaining claims of the '050 patent. From this evidence the Court finds that the accused products contain both pivot pins and a pair of slots engageable with a pair of camming members, as required by claims 11 and 12 of the '050 patent and Defendant's accused products meet claims 11 and 12 as well.

2. The '286 Patent

As to claim 8 of the '286 patent, Dr. Durfee noted that claim 8 "added" to claim 7, which has already been found infringed by the Court. (*Id.* at 334.) Dr. Durfee explained claim 8 as follows:

> [W]e need an actuator tube slidably positioned about the vibration coupler. That's the tube that moves left and right that we are talking about before, and I could see it's positioned outside the vibration coupler and it slides with respect to the vibration coupler.
>
> Then we need a distal end of the actuator tube including a cam slot. . . . So again, in the '286 patent it talks about cam slots and cam members, . . . and then again the Court's definition is the one that I used when I was analyzing cam slot and cam members.

(*Id.* at 335:2–19.) Using an ACE instrument [PTX 603], Dr. Durfee identified where on the distal end of the actuator tube the cam slots and camming members were located (*id.* at 336:7–14), showed how the actuator tube was slidably positioned about the coupler, noting that "I can move the actuator tube to retracted position by squeezing the handle, to the advanced position by letting go of the handle" (*id.* at 336:19–24), and concluded that the "ACE instrument satisfies claim 8" (*id.* at 337:2–3). At the 2007 trial, Dr. Durfee had concluded that the CS, LCS, and ACE products all satisfied the elements of claim 8. (*See* 2007 Tr. at 769–775; *see also* Durfee Expert Report [PTX 115] ¶¶ 126–28.)

Dr. Durfee also testified that claim 9 was infringed:

> On the ACE product, I'm holding on to the stationery handle, and I'm now holding on to the movable handle, which moves in relation to the stationery handle. I've also got that indicated in Figure A-36 on the screen. And then that movable handle is operably connected to the proximal end of the actuator tube because that's on the inside of the instrument.

(2012 Tr. at 337:20–338:2.) He showed a close–up cross–section photograph of the ACE instrument to demonstrate how the movable handle is "operably connected to a proximal end of the actuator tube." (*Id.* at 338:8–9.)

Claim 10 calls for a "coupling member," which the Court construed as "a component that connects two other parts." (Cl. Construction at 4.) Dr. Durfee showed a cross–section photograph of an ACE instrument and pointed out the "coupling member" that is "kind of like a collar that tightly attaches to the actuator tube, and that also connects down to the movable handle. So, it forms a connection between the actuator tube and the movable handle." (*Id.* at 339:4–8.) Dr. Durfee also opined that the CS and LCS products each have a coupling member that tightly fits to the actuator tube. (*See* 2007 Tr. 778–81.)

As to claim 11, which adds to claim 10 by requiring that the coupling member include a "swivel member," the Court construed "swivel member" to mean "a component designed to permit the coupling member to swivel or rotate." Dr. Durfee opined that "[t]he swivel member is included on the coupling member and it's an open circular slot, and it's that open circular slot that allows that coupling member to rotate in relation to the movable handle. So the ACE instrument includes the swivel member." (2012 Tr. at 340:1–6.) Dr. Durfee also opined that the CS and LCS products had a swivel member attached to the coupling member. (*See* 2007 Tr. at 782–83.)

Claim 12 requires the instrument of claim 11, with the coupling member operably connected to the rotatable knob, which Dr. Durfee testified is satisfied by the ACE products, as

> [t]he coupling member tightly wraps around the outer—the actuator tube. And the knob is pinned to the actuator tube. So, that's how the coupling member is operably connected to a rotatable knob. That rotatable knob is

> positioned next to the handle assembly. You can see it on the instrument I'm holding or you can see it in Figure A-40. And that rotatable knob is rotatably secured to the handle assembly so I can rotate it and it doesn't fall off. And you can rotate that knob in relation to the handle assembly, as I'm doing now. And as I can see, I can see the clamp member rotate. And then you can't see because it's on the inside, but because that rotatable knob is pinned to the actuator tube, which is in turn attached to the coupling member, as you rotate that rotatable knob, the coupling member also rotates.

(*Id.* at 341:2–18.) Dr. Durfee also opined that this claim limitation is satisfied in the accused CS and LCS products. (*See* Durfee Expert Report ¶¶ 138–140.)

Claim 13 requires that the rotation coupler be rotatably fixed to the rotatable knob, a limitation that is found in the ACE products. Dr. Durfee demonstrated that "when I rotate the rotation knob, . . . the vibration coupler and the cutting jaw at the distal end of the instrument also rotate, . . . and that pin goes right through the knob and right through the vibration coupler so that they all rotate together." (2012 Tr. at 342:4–12.) There are no meaningful design differences between the ACE, CS, and LCS products (*see* Durfee Expert Report at ¶¶ 141–43), and thus the Court concludes that all products are shown to satisfy the element of claim 13.

Finally, claim 14 requires an outer tube positioned about the actuator tube, with the clamp member pivotally connected to the outer tube, and the ACE products were shown to have both an outer tube and an inner, actuator tube, with the clamp member "pivotally connected," i.e., there is a pin that runs through the clamp to the outer tube, from which Dr. Durfee concluded that claim 14 was also infringed by the ACE instruments. As with claim 13 above, there are no meaningful design differences between the ACE, CS, and LCS products (*see* Durfee Expert Report at ¶¶ 144–46), and thus the Court finds that all of these accused products satisfy this claim.

3. The '544 Patent

Dr. Durfee opined that the accused products—CS, LCS, ACE, and WAVE—embody the asserted claim limitations of the '544 patent:

As to claim 1, the accused products are ultrasound surgical instruments, with an outer tube defining a longitudinal axis, with a proximal and distal end. (Durfee Expert Report ¶¶ 65–68; 2012 Tr. at 311.) The ACE and WAVE products also include an actuation member "positioned within the outer tube" (*id.* at 312) and a vibration coupler positioned within the outer tube, which has a distal and proximal end (*id.* at 313). All of the accused products have a jaw member extending from the distal end of the vibration coupler (*id.* at 314), and "a clamp pivotally mounted adjacent the distal end of the outer tube" (*id.* at 315). The clamps in the ACE and WAVE products are "movable in relation to the jaw member" (*id.*), and, using the Court's construction of the term "camming member," for the same reasons he used in his analysis of camming member in the '050 patent, Dr. Durfee concluded that the ACE and WAVE products also have camming members which operatively engage the actuation member such that movement of the actuation member pivots the clamp between the open and clamped positions (*id.* at 316–17), thus satisfying all requirements of claim 1. As discussed *supra* in connection with the claims of the '050 patent, the Court finds that the accused products contain camming members and meet the remaining elements of claim 1 as well.

Dr. Durfee concluded that claim 2 of the '544, which requires an ultrasonic instrument of claim 1, "wherein the actuation member includes a slot for receiving the camming member of the clamp," was satisfied by the slots on the actuation members of the ACE and WAVE products (*id.* at 318; *see also* Figs A-51, B-10), which the Court also

finds. Claim 3, which depends on the presence of "cam slots" is found to be satisfied by the ACE and WAVE products.

The remaining claims of the '544 patent build on these earlier dependent and independent claims, and Dr. Durfee testified that the limitations of claims 9–13, 16, 18, 23–25 are met by the accused products. Each of these claims disclose limitations similar to those already found in the asserted claims of the '050 patent, and Dr. Durfee showed how both the ACE products embody the limitations of claims 9 (handle assembly), 10 (rotatable collar), 11 (clamp and jaw member rotatable about the longitudinal axis of outer tube), 12 (rotatable collar adjacent to handle assembly), 13 (transducer removably supported on the handle assembly), 16 (transducer horn adapted to engage a proximal end of vibration coupler), 18 (outer tube dimension to be received within a 5mm trocar assembly), 23 (at least one tissue receiving stop), 24 (jaw member and blade surface having a proximal and distal end with at least one tissue receiving stop next to proximal end of blade surface), and 25 (clamp pivotally mounted on distal end of outer tube). (*See id.* at 322–332). During the 2007 phase of the trial, Dr. Durfee demonstrated how, in his opinion, the accused ACE, CS, and LCS products met all of the above claim limitations. Dr. Cimino's dispute was limited to his view that no cam mechanism can be found in the accused products. (*See, e.g.*, 2007 Tr. at 741.)

Dr. Durfee also opined, which Dr. Cimino did not dispute, that the WAVE products satisfied the limitations of claims 9 and 13 (2012 Tr. at 326:5–5 ("[T]he transducer screws into the back of the WAVE and is supported on to the handle assembly.")), 16 (Durfee Expert Report ¶ 91 ("[T]he WAVE instruments have no meaningful design differences when compared to the ACE instruments, and contain the claim element.")), and 25 (*id.* ¶ 96.)

Claims 6 and 8 of the '544 patent describe specifications as to the jaw member and cutting surface of the instrument. Dr. Durfee testified that after examining the attributes of the accused CS, LCS, and ACE products, it was his opinion that they infringed claims 6 and 8 of the '544 patent.

As to Claim 6,

> [Claim 6] calls for a jaw member including a—well, it adds to claim 1, and then it calls also for a jaw member that includes a curved blade surface. . . . It is found in the ACE product. . . . I can see that the jaw member is curved.

(2012 Tr. at 320:6–15; *see also* 2007 Tr. at 735:17–25.) Dr. Durfee also pointed out a close–up photograph of an ACE product [Fig. A-53], in which the blade surface visibly curved downward. The Court finds that the accused ACE, CS, and LCS products have jaw members that include a curved blade surface.

As to claim 8, the "curved blade surface" must include a "longitudinally extending cutting edge," which the Court construed to mean "the edge of the blade surface designed for cutting that extends along the lengthwise dimension." (Cl. Construction at 34.) Pointing to the same close–up photograph, Dr. Durfee explained how the cutting edge of the blade surface extended longitudinally:

> It means that as you imagine yourself travelling along that cutting edge from proximal to distal end, you are going to be walking along a curved path, but as you walk, you are continually moving forward. So, you are curving and moving forward in the lengthwise dimension. So, that's why it's a longitudinally extending cutting edge on the ACE instrument, and this is figure A-54 that I'm referring to.

(2012 Tr. at 321:17–25.) Dr. Durfee also opined that the accused CS and LCS products had no meaningful design differences with respect to this claim, and satisfied claim 8 of the '544 patent. (*See* 2007 Tr. at 737–38.)

In sum, Dr. Durfee testified that he found that all the asserted claims of the '544 patent either were infringed by the CS, LCS, and the ACE or by the ACE and the Harmonic WAVE. (2012 Tr. at 333.) Based on the Court's above conclusion that the accused products possess a camming mechanism as contained in the '544 patent and construed by the Court, the Court finds that the contested camming elements of the '544 patent are satisfied by the CS, LCS, ACE, and WAVE products. The Court also finds that the CS, LCS, and ACE products meet the claim limitations of claims 6 and 8.

B. Discussion and Conclusions of Law on Infringement

Infringement analysis entails a two–step process: "First, the court determines the scope and meaning of the patent claims asserted . . . and second, the properly construed claims are compared to the allegedly infringing device." *Planet Bingo, LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1341 (Fed. Cir. 2006) (internal citations and alterations omitted). "[F]or a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device." *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1384 (Fed. Cir. 2005) (internal citations omitted). To prove infringement, Plaintiffs must meet the "usual civil law standard," that is, proof by a preponderance of the evidence. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F. 3d 1316, 1327 (Fed. Cir. 2008).

The only testimony Defendant offered at trial to oppose Plaintiffs' claims of infringement focused on whether the accused products contained camming mechanisms. Under this Court's construction, the camming mechanism disclosed by the asserted claims must have "openings or grooves that impart motion to and guide the motion of the camming members." (Cl. Construction at 11.) As Dr. Durfee testified, even if the mechanisms disclosed in the patent and in the accused devices look different, there is no

requirement that the mechanisms contained in the accused devices contain a mechanism that looks precisely like the embodiment in the patent. It can still be the same mechanism, and "absent a clear disclaimer in the specification, the embodiments in the specification do not limit broader claim language." *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1336 (Fed. Cir. 2005).

In post–trial briefing, Defendant contends that because Dr. Durfee testified on rebuttal that the single–toothed gear shown by Dr. Cimino could be both part of a rack–and–pinion mechanism and a cam mechanism, his infringement opinion that the accused devices contain camming mechanisms should be disregarded. However, Defendant has not offered evidence to explain why a device could not, as Dr. Durfee has opined, have both the characteristics of a single–toothed gear and a cam mechanism. That the particular mechanism employed in the Defendant's accused products may share characteristics with both a cam and rack and pinion does not have any bearing on the Court's task in its infringement analysis, which is to inquire whether every element of the claims at issue is present in the accused devices. *Planet Bingo*, 472 F.3d at 1341.

As discussed above, the Court finds that Plaintiffs have met their burden of proving by a preponderance of the evidence that the mechanism contained in the accused devices is a cam mechanism. Further, Defendant offered no testimony as to non–infringement of claim 10 of the '050 patent regarding a "sealing ring," or as to claims 10–13 of the '286 patent concerning the "coupling" and "swivel" member, or as to claims 6 and 8 of the '544 patent, which require a curved blade surface, and, as discussed above, the Court finds it more likely than not that the accused devices meet all of these claim limitations.

Accordingly, the Court finds that Tyco has proved that the accused CS, LCS, and ACE products have every element of claims 10, 11, and 12 of the '050 patent, and thus finds these claims infringed. The Court also finds that Tyco has established that claims 8–14 of the '286 patent are present in the CS, LCS, and ACE products, and thus that these claims are infringed. Finally, Tyco has shown that the CS, LCS, and ACE products infringe claims 1–3, 6, 8, 9–13, 16, 18, and 23–25 of the '544 patent, and that the WAVE 18S infringes claims 1–3, 9, 13, 16, and 25 of the '544 patent.

IV. Invalidity

These parties are neck–and–neck competitors whose race to create and patent in the advanced energy surgical device field can be seen from the following descriptions of the trajectories of their respective stages of development. These stages of development form the basis of Defendant's claims that Tyco's patents are invalid because of prior invention and obviousness. The Court addresses Ethicon's defense of prior invention under 35 U.S.C. § 102(g) first, and then its 35 U.S.C. § 103 defense of obviousness.

A. Prior Invention Defense Under 35 U.S.C. § 102(g)

Ethicon asserts that claims 1, 5, 9–10 of the '050 patent, claims 1, 6, 7, and 8–14 of the '286 patent, and claims 1, 2, 9–13, 16, 18, and 23–25 of the '544 patent are invalid on account of their prior art. Drs. Cimino and Durfee were in agreement that Defendant's prototypes all contain those claims. Ethicon also contends, but Tyco disputes, that the curved blade claims—claim 15 of the '286 patent and claims 6 and 8 of the '544 patent are invalid because of the blades contained in the UltraCision and Ethicon prototypes.

1. Factual Findings

Ethicon's witnesses Dr. Tom Davison, Mark Tsonton, Gary Whipple, Dr. Joseph Amaral, and Dr. Laura Gallagher testified extensively about the development and testing on the harmonic instruments created by Ethicon in the mid–1990s. In the late 1980s, Dr. Tom Davison, an entrepreneur with a PhD in physiology, began to investigate the potential for using ultrasonic energy to cut and coagulate tissue in laparoscopic surgical procedures (*see* 2007 Tr. at 1285:9–1287:21), and formed Ultracision, Inc. in 1988 for the purpose of exploring and developing ultrasonic laparoscopic surgical tools (*id.* at 1287:22–1291:2). The ultrasonic instruments that Dr. Davison and his partners were working on use a generator that provides power to a transducer, and the transducer is coupled to an elongate metal rod called a vibration coupler (*see id.* at 1647:14–1649:3), with the ultrasonic vibrations carried from the proximal end of the vibration coupler to the distal end, causing the tool to vibrate very rapidly (*id.* at 1783:16–1784:17). Dr. Davison testified that UltraCision introduced the first commercial, ultrasonic surgical instrument, the LCS10, in 1993. (*Id.* at 1301:9–20.) In 1995, Ethicon–EndoSurgery acquired UltraCision.

The LCS10 was a 10–millimeter surgical device that used ultrasonic energy. As disclosed in the Davison Patent No. 5,322,055 ("'055 patent," or "Davison patent" [DTX 1169]), it had a curved blade, a curved blade surface, a clamp and clamping surface, a removable transducer, tissue stop, an actuation rod, a pair of pivot pins, and a rotation knob. (*See* Fig. 1a, '055 Patent.) Gary Whipple testified that he drew a picture of a prototype of a "5–millimeter version of the 10" that was developed at UltraCision (2007 Tr. at 1363:7–8), and that picture was dated May 17, 1996 (*id.* at 1367:11).

The earliest date that Tyco has alleged that it conceived of its product is January 8, 1997, and Tyco maintains that it reduced its invention to practice as of March 10, 1997. (*See* Joint Timeline [Doc. # 223] at 2; *see also* Surgical Response to Requests for Admission Nos. 1 & 2 [DTX 1700].) It is undisputed by the parties, and the Court finds, that this "UltraCision Prototype" was an ultrasonic instrument created for the goal of cutting and coagulating tissue, in the same manner as the LCS10, but with the ability to fit down a 5mm trocar, and that it was developed prior to Tyco's invention. It is similarly undisputed that the Ethicon Prototype was conceived of in a drawing dated November 22, 1996, and that the physical prototype went through a series of tests and modifications subsequent to that date. The only dispute at trial was whether either of these prototypes actually worked for its intended purpose, and/or whether Ethicon's changes in these prototypes constituted "abandonment" of these initial conceptions, such that their ultimate release of the LSC5 was sufficiently different so as to not constitute "prior" art.

a) UltraCision Prototype

Dr. Joseph Amaral, a doctor trained in clinical surgery and the former President of Rhode Island Hospital, who assisted with the testing of the UltraCision prototype, testified at the 2007 portion of the trial that when Ethicon first acquired UltraCision back in 1995, the 5–millimeter product was already working. (2007 Tr. at 1544:9–1544–20.) He testified further that:

> The product as it existed back after the acquisition worked effectively, but my interpretation what was going on is that Ethicon was also trying to understand the technology, so there were a lot of iterations that were going on . . . one might clamp better, one might grasp better, one might do this better, and I remember being frustrated thinking, "Can't you just release this thing," and . . . I really felt pretty strongly about that, because the really significant thing about this device was that it was 5–millimeter and it was a lot easier to see. . . . So there was an iterative process going on, and it

> was frustrating, because it worked right—it worked early, right when they bought it.

(*Id.* at 1545:24–1546:14.) He testified that very early on, prior to Ethicon's announcement that it had acquired UltraCision, he did a demonstration for Ethicon in which he successfully "divided" the iliac artery in a pig with the UltraCision 5mm prototype. (*Id.* at 1543:15–1544:3.)

Dr. Laura Gallagher, Clinical Research Director at Ethicon and a trained Doctor of Veterinary Medicine, testified that between 1995 and 1998 she was responsible for the UltraCision projects, and that she "learned about the technology and observed surgery out in the field, identified the methods . . . to test the products, develop the animal models and tested the products in preparation for 510(k) [FDA] submission." (2012 Tr. at 428:10–14.) Dr. Gallagher testified that there were two "teams" working on the "UT5.5 team"—a Cincinnati team, of which she was a member, and a Smithfield team, of which "lead engineers" Gary Whipple and Paul Smith were members. (*Id.* at 434–35.) She testified that they kept diligent notes and submitted weekly reports documenting the progress of their tests. (*See, e.g.*, Weekly Reports [DTX 1383–1459].)

In 1996, a number of tests were performed on porcine models by Dr. Gallagher and her team. She testified that "[t]he pig model is the standard for evaluating medical devices and the standard that we use for training surgeons with the technology." (*Id.* at 444:8–10.) For example, in a test performed in April 1996, Dr. Gallagher identified the objective as "see[ing] how [the prototype] performed in ligating and transecting vessels and soft tissue, and it was fired on the jejunal mesentery and ovarian pedicle, vascular structures in the abdomen of the pig." (*Id.* at 444:14–18.) The results were that "[t]he

prototype achieved good hemostasis[7] on the jejunal mesentery and the ovarian pedicle" (*see* April 1996 Lab [DTX 1460] at 3). The prototype was also applied to the renal vein, which was measured to be approximately 4–5mm in diameter, but hemostasis was not achieved on this larger vessel. (*Id.* at 3.) Dr. Gallagher reflected that she was not surprised that hemostasis was not achieved on this "very large" vessel, stating, "[w]e knew it was a large vessel and it was a severe test of the device." (2012 Tr. at 446:24–25.)

Over the course of performing tests similar to the April 1996 test (*see, e.g*, July 1996 Lab [DTX 1461]), Dr. Gallagher and her team developed a grading scale that specifically addressed the transection (or cutting) profile and the hemostasis profile. She testified that while these standards were not "industry standards," they helped her and her team to "be consistent in recording what [they] observed" (*id.* at 453:6–13). She testified that in terms of the hemostasis profile, on a scale of 1 to 5, "1 through 3 were considered acceptable and would represent what a surgeon might see in a case and be able to address." (*Id.* at 454:4–7.) By the end of July 1996, Dr. Gallagher sent an email to the rest of the UT5.5 team (*see* 7/31/96 Email [DTX 1462]) recommending that they invite different surgeons from various specialty areas in order to solicit their feedback. She testified that her recommendation to solicit outside feedback meant that "the prototypes were working well and that it was worth the time of the surgeons to come in and take a look at them and give us feedback." (2012 Tr. at 456:20–23.)

On some occasions, the devices did not perform as intended. For example, during an evaluation performed by an outside surgeon on August 23, 1996, two of the devices had problems: the UTD #3 device "generated a solid tone," which indicated that the blade

[7] "Hemostasis" means "no bleeding, or an effective vessel seal" (2012 Tr. at 445:14–15).

was not able to move appropriately (*see* 8/23/96 Evaluation [DTX 1463]); *see also* 2012 Tr. at 460:7–11), and the UTD #7 device's "Teflon pad" that is attached to the clamp arm "curled off after 1 or 2 applications" of the device to the animal model (*see* DTX 1463 at 3). During that particular evaluation, only the UTK device "functioned acceptably" and was used for the dissection. (*Id.*) The individual UltraCision prototype devices were reused over the course of testing, and Dr. Gallagher explained that "[i]t was very routine to use them more than once. They were few in number and . . . considered precious, basically assembled by hand. Each one was unique and very unlike a manufactured device where it would have gone through very rigorous specifications for manufacturing." (2012 Tr. at 463.) Dr. Gallagher testified that in general, ultrasonic devices are "intended to be used for one surgery, but . . . we used these multiple times due to the limited quantity." (*Id.* at 463:10–13.)

Overall, it was Dr. Gallagher's testimony, corroborating the record of successful tests on porcine models, that the Ultracision prototypes worked to cut and coagulate small vessels as of late 1996. (*See, e.g.*, September 1996 Lab [DTX 1465].) She testified that while her team discussed whether to launch the product in December 1996, "[t]he decision was made to not launch the product . . . solely for smaller vessels. Again, our predicate device was the LCS–10. That device was approved for use in vessels up to—actually including 3mm, and we had not demonstrated the capability of these devices to seal larger vessels in the labs up to this point." (2012 Tr. at 483:1–7.)

b) Ethicon Prototype

According to mechanical engineer Marc Tsonton, in November 1996, the Ethicon prototype design was completed, as corroborated by an "exploded view drawing of a UT5.5 from the Ethicon design" dated November 22, 1996. (2007 Tr. at 1658:16–17; *see*

also UT5.5 Drawaing [DTX 1791].) Mr. Tsonton described the decision to "make changes to the design of . . . the original UltraCision prototype" (2007 Tr. at 1652:18–20), and testified that the goal was "to improve the manufacturability, to improve the ergonomics of the device and to overall reduce part count" (*id.* at 1652:23–1653:1). When asked what specific changes were made to the prototypes, he testified, "[t]here were changes made at the clamp arm attachment configuration. There were changes made to the detent mechanism that was in the handle. There were ergonomic changes made to the rotation knob and to the general handle configuration." (*Id.* at 1653:3–8.) Mr. Tsonton testified that these changes did not affect the instrument's tube–within–a–tube design, its ability to fit through a 5–millimeter trocar, or its rotation knob and handle mechanism. (*Id.* at 1656.) He stated that his team made the "first batches" of Ethicon prototypes in December 1996. (*Id.* at 1657.) He also noted that "changes were made throughout the program. As we developed and we learned more about the device and how it interacted in tissue, we would make minor modifications to it." (*Id.* at 1679.)

When asked by the Court about the extent of the changes between the UltraCision and Ethicon prototypes, Dr. Gallagher testified that she

> wanted to remain unbiased to what the changes were to the device[s] when they brought them into the lab. They had a . . . parts list or a description of the device, but I didn't know what was different about it. So, I would use it in a normal fashion and observe what was occurring. So, there were times when I wasn't aware, and certainly wasn't aware if it was anything besides the blade that had changed.

(*Id.* at 722:23–723:8.)

Dr. Gallagher testified about a February 1997 lab conducted by Dr. Amaral, in which he performed an ovario–hysterectomy on a goat model, in which she assisted, using an Ethicon prototype. (*See* 2012 Tr. at 484:21–22; *see also* DVD [DTX 1182].) Dr.

Gallagher testified that "[a]s is often the case, at the end of the lab, you know, there is an interest to place the device on a large vessel, and so he fires it across the iliac artery of the goat." (2012 Tr. at 485:24–486:2.) She estimated that the iliac artery that he was able to cut and seal successfully was approximately three millimeters in size. (*Id.* at 486:6.) Dr. Gallagher noted that once Dr. Amaral had cut across the iliac artery, in order to "severely" test the quality of the seal that he had created, he asked that the animal be given epinephrine to elevate the animal's blood pressure. (*Id.* at 488.) Under these "severe conditions," the Ethicon prototype was able to cut and seal the right iliac artery. (*Id.* at 489:15–19.)

Mr. Tsonton testified on cross–examination that in July 1997, the UT5.5 team met and discussed whether there was a design with which "it could move forward with the release or whether it needed to take a step back and do additional research" (2007 Tr. at 1766:8–13), and that they concluded that additional research and brainstorming was required (*id.* at 1766). Ultimately, the UT5.5 team prepared a 510(k) submission for the FDA on January 9, 1998. (*See* 2012 Tr. at 565:1–3.) They received notice from the FDA that their submission was approved on April 20, 1998 (*see* DTX 1817 at EES0253636), and Ethicon launched its first two 5mm products, the LCS–B5 and LCS–K5, later that year. Tyco had filed for FDA approval in May 1997, and received FDA approval and introduced AutoSonix to the commercial market in July 1997. (*See* Joint Timeline [Doc. # 223] at 2.) As discussed above, Tyco filed its patent applications for the '050, '286, and '544 patents on August 14, 1997. (*Id.* at 3.)

c) Issues with the Prototypes

Tyco points to Ethicon's President's Award Submission [DTX 1538], which Dr. Gallagher described as "includ[ing] the story of the development of the 5–millimeter

prototypes," to show that the prototypes were unable to successfully cut and coagulate, that is, achieve their intended purpose. The President's Quality Award Submission was described by Dr. Gallagher as "a contest of demonstrating proper use of processes, quality processes to assess—identify a problem, effectively look at the causal elements of it, and then create a plan to address those problems and demonstrate ultimately a successful device from that with an impact on the market" (2012 Tr. at 568:6–12). Dr. Gallagher further defined their "submission" as "demonstrating . . . what the issues were before we established that process in some, you know, rigidity requirements around the process, and what happened after we did." (*Id.* at 569:14–18.) The document identifies the "themes": the "LCS–5 prototypes created poor vessel seals in the animal model compared to the predicate device, the LCS–10. Modified LCS–5 prototype designs also failed to create effective vessel seals," and "the team needed a method to quickly identify critical design parameters and to rapidly screen prototypes." (President's Quality Award Submission ("PQA") [DTX 1538] at EES0151216.)

When asked about the document, Dr. Gallagher testified that she did not recall any major issues with regard to the cutting and coagulation of small vessels, but she conceded that, as disclosed in the President's Award Submission, "[t]he prototype LCS–5 caused tissue sticking, smoke production obscuring laparoscopic visualization, and undesirable thermal injury to tissues. The prototype blade was so hot Teflon clamp pads were melting, and in some instances, the blade itself melted." (*Id.*) She explained,

> A: [I]t was during evaluation early on of the prototypes, you know, and we—I certainly didn't appreciate it. I think the team didn't appreciate it when we were using these prototypes in an abusive mode. Just reusing them was abusive over and over again. And so in some instances we had the Teflon pads fall off or melt because of the heat generated by the blade. And in one instance, I don't recall exactly what I was doing, but the blade itself got so hot it kind of deformed.

> Q: And, again, in general what were the testing conditions under which these devices were tested in terms of their severity?
>
> A: Yeah, this was under very abusive, severe conditions that this occurred.

(2012 Tr. at 571:11–25.) Dr. Gallagher also emphasized on cross–examination that the document was focused exclusively on a summary of her team's work on the 5–millimeter prototypes with respect to goat models and larger vessels, as opposed to porcine models and smaller vessels. (*See id.* at 581.)

The President's Quality Award Submission does not state during what time frame these particular challenges with the devices occurred, but Dr. Gallagher testified that it was early on in their learning process. (*See id.* at 589:4–14.)

As part of the "solution planning and implementation" of the prototype evaluation process identified in the Submission, the document describes that "[a] rapid prototype performance screening (RPPS) was proposed," and it included "[Reliability Development Lab], Excised Tissue Lab (porcine carotid arteries), Acute Animal Studies, and Survival Animal Studies." (PQA at EES0151217.) The "tangible results" identified were:

> [h]emostasis performance was demonstrated to be equivalent to the LSC–10 . . . . No reports of post–operative hemorrhage have been received.
> A successful product was released to the market that has exceeded sales projections. . . .
>
> Intellectual property/trade secrets in the form of critical design parameters for UltraCision shears devices (the science of the technology) was discovered . . .
>
> The combination of attributes critical to quality for all UltraCision clamping instruments was identified . . .

> Prototype evaluation cycle time was reduced from an estimated 2 years to six months.
>
> The RPPS process supported the rapid characterization and performance evaluation of a large number of prototypes.

(*Id.* at EES0151219.)

On cross–examination, Dr. Gallagher again went through the majority of the goat labs that she had deemed "acceptable," and was questioned about the various failures or issues that presented themselves during the labs. She had testified that the goat laparoscopic abdominal hysterectomy (LAH) procedure was "considered to be . . . the optimal model for testing vessel seals, yes, because . . . the tissue and vessels sizes were the closest to that of a human." (2012 Tr. at 586.) Ethicon's Wetlab Summary [DTX 1539] reveals that of the fourteen goat labs performed with the UltraCision prototypes, eleven reported issues of "hemorrhage." (*See* Wetlab Summary at EEZ00141217.) The Wetlab Summary also reports additional issues, including tissue sticking, tissue charring, smoke production,[8] hot blade, and generator lock–out. (*Id.*) These problems existed in the prototypes which received satisfactory ratings in the labs, which Dr. Gallagher explained: "The rating is at the initial transection. The intraoperative period is the period between . . . performing the transection and moving into the blood pressure challenge." (2012 Tr. at 659.) Dr. Gallagher testified that it was considered "acceptable" to perform subsequent applications, or "touch ups," of the test device[9] in order to control oozing of blood during

[8] Ethicon's witnesses, including Dr. Gallagher, clarify that the term "smoke" is a misnomer, and that in fact "steam" or "vapor" would be a more apt description of that particular issue, as opposed to where there is a "very hot blade and tissue is being burned or charred, [which] can be smoke as we know it on the barbecue." (2012 Tr. at 692:8–16.)

[9] Dr. Gallagher described a "touch up" as follows: "A touch up is basically taking the point of bleeding in your site of interest and grasping it in the tip and compressing it

a lab (*id.* at 711), and that in fact, "it's very common" in surgery on humans as well, and it is "expected that you are going to do those little touch ups" (*id.* at 724:14–22).

When asked why the devices, as they were received in 1995/1996, were not ready for manufacturing and "rapid market release," Dr. Gallagher explained that the devices "were not functioning well in the goat model," (*id.* at 714), but that ultimately, it was her opinion that the UltraCision and Ethicon prototypes performed acceptably in cutting and sealing vessels of less than 2 millimeters in size (*id.* at 717). She noted that the problems were "associated with the large vessels sizes 2 to 3 mm or greater." (*Id.* at 718:25–718:2.) Though Dr. Gallagher's testimony is that her team was concerned with successfully cutting and coagulating of larger vessels, it was not until the September 11, 1997 lab that Ethicon began recording vessel sizes. (*See* PQA at EES0039310.)

d) Expert Testimony on the Comparison Between Prototypes and Patent Claims

The parties' experts are in agreement that features in the specific claims in suit are "present in the protoypes." (2012 Tr. at 1755; *see also* Durfee Rebuttal Presentation [PTX 694].) The Court credits their opinions.[10]

The only claims about which Dr. Cimino and Dr. Durfee disagree are the curved blade claims: claim 15 of the '286 patent and claims 6 and 8 of the '544 patent. Dr. Cimino testified that both prototypes have a cutting surface that's "curved along the longitudinal axis," which would satisfy the curved blade claims in suit. He pointed to the "spherical

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and firing for a short period of time. So, it's just a short application of energy to seal that little bit that's bleeding." (*Id.* at 724:5–10.)

[10] Thus, Dr. Cimino and Durfee agree that the prototypes contain claims 1, 5, and 9–10 of the '050 patent, claims 1, 6, 7, and 8–14 of the '286 patent, and claims 1, 2, 9–13, 16, 18, and 23–25 of the '544 patent. (Durfee Rebuttal Presentation.)

tip" of the prototype blades as evidence of a curved blade surface, and also noted that the prototype blades have a "circular cross–section," which he testified supported his opinion that the prototype blades anticipated the curved blade claims in the '286 and '544 patents.

Dr. Durfee opined that the prototype blades, which he described as "roughly cylindrical in shape," were straight blades. He testified that the prototype blades have "no deviation from a straight line and no curve." (2012 Tr. at 1758:19–22.) The Court agrees with Dr. Durfee's description of the prototype blades. In comparing the prototype blades and the asserted patent claims requiring a "blade surface that has a deviation from a straight line," and "a longitudinally extending cutting surface," the prototype blades do not deviate from a straight line. While they may be angled downward (*see, e.g.*, DTX1683-014), they are still straight lines and therefore do not "deviate from a straight line." Thus, even with the "spherical tip" and "circular cross section," the Court finds that the prototype blades do not possess features matching the curved blade claims of the '286 and '544 patents.

B. Discussion and Conclusions of Law as to 35 U.S.C. § 102(g)

"In determining priority of invention . . . , there shall be considered not only the respective dates of conception and reduction to practice of the invention, but *also reasonable diligence of one who was first to conceive and last to reduce to practice*, from a time prior to conception by the other." 35 U.S.C. § 102(g)(2) (emphasis added). A challenger of a patent must prove "by clear and convincing evidence" that the invention was made in this country by another inventor. *See Apotex USA, Inc. v. Merk & Co., Inc.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001).[11]

[11] "The 'clear and convincing' standard is an intermediate standard which lies somewhere in between the 'beyond a reasonable doubt' and the 'preponderance of the

1. Prior Conception

"Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative inventions, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Burroughs Welcome Co. v. Barr Labs.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994).

In determining prior conception, "an inventor need not know that his invention will work for conception to be complete . . . [he] need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice." *Burroughs*, 40 F.3d at 1228.

Tyco focuses on the multitude of changes and improvements made to Defendant's prototypes' design, and contends that Ethicon's conduct defeats a finding of prior conception, because Defendant's idea was "in constant flux." (Pl.'s Mot. [Doc. # 210] at 16.) However, the Federal Circuit has found conception with far less physical evidence than was presented in this trial. For example, notebook entries, supported by testimony by an inventor and non–inventor, were sufficient to establish conception. *See Spansion, Inc. v. International Trade Comm'n*, 629 F.3d 1331, 1356–57 (Fed. Cir. 2010) ("Because it is a mental act, an inventor's oral testimony regarding conception must be corroborated by "evidence which shows that the inventor disclosed to others his completed thought

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evidence standards of proof.'" *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 n.5 (Fed. Cir. 2007). "Clear and convincing evidence may be described as evidence that 'place[s] in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable.'" *Id.* (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

expressed in such clear terms as to enable those skilled in the art to make the invention."). It is a "mental act." *Id.*

It is undisputed that the UltraCision and Ethicon prototypes existed in the form of detailed drawings and physical embodiments in 1996, before Tyco's earliest conception date in January 1997. These drawings and embodiments, corroborated from testimony by Dr. Davison, Mr. Tsonton, Dr. Amaral, and Dr. Gallagher establish a "definite and permanent idea" of the operative invention—an ultrasonic instrument that could fit down a 5–millimeter trocar and could cut and coagulate in surgery. Ethicon also notes that the elements that it relies on to establish anticipation of the claims in suit—tube in tube design, rotation, and "cams"[12]—were present in each embodiment of the prototypes Ethicon tested between 1996 and 1998. (*See* Whipple Test., 2007 Tr. at 1343–67.)

The question, for the Court therefore, is whether the professed goal of the UT5.5 project, which was to create a 5–millimeter ultrasonic instrument that worked as well as the LCS10 was sufficiently developed to support conception, rather than "just a general goal or research plan." *see Burroughs*, 40 F.3d at 1228. "Whether or not subsequent testing succeeded or failed, or even took place, does not determine whether conception was complete as of that date." *In re Jolley*, 308 F.3d 1317, 1326 (Fed. Cir. 2002).

While the evidence shows that Ethicon worked hard to reduce this conception to practice through years of testing, this does not mean that the mental act of conception was not accomplished. *See Burroughs*, 40 F.3d at 1228 ("[T]he discovery that an invention actually works is part of its reduction to practice.") The intention of the Ethicon and

[12] Dr. Cimino testified that while he maintained that the mechanisms in the accused products were not cams, his opinion is that assuming Dr. Durfee's analysis with respect to the cam components, the mechanisms in the prototypes are "cams" for the purposes of Ethicon's § 102(g) defense.

Ultracision engineers was to create a 5–millimeter ultrasonic instrument that worked as well as the LCS10. This is "objective evidence of what the inventor[s] ha[d] disclosed to others, and what that disclosure would fairly suggest to one of ordinary skill in the art." *See In re Jolley*, 308 F.3d at 1323. The evidence at trial certainly shows that the evolution from the UltraCision and Ethicon prototypes to the LCSK and LCSB that were released commercially involved modifications—to the blade size (*see* 2007 Tr. at 1701:18 ("The team was trying to take advantage of all of the work that had already been done . . . . So we were trying to fit an 085 blade into the existing platform that we had already created and depicted in the November 1996 drawing)), and to the clamp arm over the course of a month in July–August 1997 that changed the prototypes from two pins to four pins/single tab to double tab—but the ultimate goal remained steadfast throughout efforts to reduce this invention to practice.

The facts here are readily distinguishable from cases in which an idea "is in constant flux," of where there is "uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs*, 40 F.3d at 1229. The Court finds that it is highly probable that Ethicon's prototype designs, corroborated by the testimony of Ethicon's engineers establish conception prior to Tyco's January 1997 date.

2. Reduction to Practice

"In order to establish reduction to practice, the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Teva Pharmaceutical Indus. Ltd. v. AstraZeneca Pharmaceuticals LP*, 661 F.3d 1378, 1383 (Fed. Cir. 2011). "When testing is necessary to show proof of actual reduction to practice, the

embodiment relied upon as evidence of priority must actually work for its intended purpose." *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994).

A significant issue of contention at trial was whether the prototypes "actually work[ed] for their intended purpose." It was unclear whether the intended purpose of the prototypes was to cut and coagulate small vessels *and* large vessels, or whether it was enough that Ethicon's prototypes worked with small vessels of 1 to 2 millimeters. Ethicon emphasizes that Tyco itself, in its own submission to the FDA, provided testing data for successful transection and coagulation only on small vessels. (*See* Tyco 510(K) Submission [DTX 1336] at USS005114; *see also* 2007 Tr. at 651:3–9.) Further, Ethicon's witnesses Dr. Gallagher and Mr. Tsonton testified that the intended goals of the prototypes were that the devices perform at least as well as the LCS10 (2012 Tr. 732:13–17), and that the devices be able to effectively cut and coagulate vessels during surgery (2007 Tr. at 1316–17). Though Ethicon's stated goals in testing may have been to consistently cut and coagulate large vessels, the Court concludes that the "intended purpose" of the prototypes, for the reduction to practice analysis, is only that the devices be able to effectively cut and coagulate during surgery, and that the details of vessel size are largely irrelevant.

It is clear that some of the tests went extremely well, such as the February 1997 test in which Dr. Amaral successfully cut and sealed a 3–millimeter vessel, and then further successfully subjected the vessel to the severe conditions of a "blood pressure challenge." (*See* DVD [DTX 1184]; 2012 Tr. 484:7–489:19.) However, it is also clear that in the survival studies, i.e., the more intensive, longer term tests, there were failures of the devices. (*See, e.g.*, July 1997 Survival Study [DTX 1477]; 2012 Tr. at 541:9–14.) Dr. Gallagher testified that at the survival study performed on July 9, 1997, "[w]e were not

able to achieve hemostasis under the very severe blood pressure challenge criteria in [one] animal." (2012 Tr. at 541.) While there is no requirement that an invention be "in a commercially satisfactory stage of development" in order to reduce that invention to practice, *see, e.g.*, *DSL Dynamic Sciences Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1126 (Fed. Cir. 1991), testing must show "utility beyond a probability of failure," *Scott v. Finney*, 34 F.3d at 1061.

Ethicon has demonstrated that, through significant testing, the devices were deemed "acceptable" by Ethicon's own doctors and engineers both on large and small vessels. However, Dr. Gallagher also conceded that those ratings did not mean that the devices were consistently able to cut and coagulate vessels without the possibility of hemorrhaging, as the rating only described the "initial transection."

Defendant points out that the "unacceptable" results highlighted by Tyco involved experimentation with the tip amplitude of the prototype, which Dr. Gallagher explained: "We wanted to see what would happen. We wanted to see what the tissue effect was, essentially, and it would help us define the specifications for the LCS–K design. So, what the range of amplitude could be on the blade." (2012 Tr. 531:1–6.) Dr. Gallagher also repeatedly stated in her testimony that they were pushing the devices beyond what they were intended to do, by reusing them over and over again and designing tests to "force failure." (*See, e.g.*, *id.* at 490, 505, 613.)

However, that Defendant's tests required the prototypes to perform under "severe" conditions, under which the prototypes did not always perform "acceptably," does not necessarily mean that the prototypes were capable of working for their intended purpose earlier than Plaintiff's earliest reduction to practice date of March 1997. Rather, the multiple rounds and years of testing reveal that Ethicon was working tirelessly to

achieve a specific result, one that the team members did not feel they had achieved by that time. Compounding this is the fact that the "story" of the prototypes recounted in the President's Quality Award Submission document lacks any meaningful dates. The document details the early struggles with the prototypes, and it also gives an account of the eventual success of the prototypes; however, the date of the document's submission is March 1999, and no clear detail is provided as to when, precisely, the documented successes took place.

Defendant maintains that an "invention can be reduced to practice even though the inventor may have encountered failures when testing his or her invention to determine its performance limitations." (Def.'s Mot. [Doc. # 209] at 14 n.8 (citing *Hradel v. Griffith*, 367 F.2d 851, 8551 (CCPA 1966) ("Appellants were seeking an insensitive explosive; their work naturally involved failures to detonate.").) However, Ethicon does not show how its tests attempting to "force failure," which did yield failures of the devices, including charring, trouble grasping, generator lock out, and incidences of intraoperative hemorrhage, would enable the Court to extrapolate that they had achieved their goal of a device that can cut and coagulate "beyond a probability of failure." Further, as discussed above, though it appears highly probable that Ethicon's prototype conception date pre–dates Plaintiff's earliest possible date of conception, there is insufficient evidence from which to find that it is highly probable that Defendant's devices were reduced to practice prior to Plaintiff's March 1997 reduction to practice date.

Accordingly, the Court finds that Ethicon has not proven by clear and convincing evidence its § 102(g) defense by proving prior reduction to practice.

3. Reasonable Diligence, Lack of Abandonment, Concealment

Ethicon argues that even if the Court were to find that they had not reduced their prototypes to practice prior to Tyco, they were first to conceive, and continued to work with reasonable diligence from April 1996 through their Patent filing in October 1997, so that they are still entitled to a full § 102(g) defense.

a) Diligence

"[A] showing of diligence is necessary for a party who was first to conceive the invention, but second to reduce it to practice. The time period for which diligence must be shown by the party first to conceive is 'from a date just prior to the other party's conception to . . . [the date of] reduction to practice [by the party first to conceive].'" *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1362–63 (Fed. Cir. 2001) (citations omitted) (alterations in original). "Unlike the legal rigor of conception and reduction to practice, diligence and its corroboration may be shown by a variety of activities." *Brown v. Barbacid*, 436 F.3d 1376, 1382 (Fed. Cir. 2006). "The basic inquiry is whether, on all of the evidence, there was reasonable continuing activity to reduce the invention to practice. There is no rule requiring a specific kind of activity in determining whether the applicant was reasonably diligent in proceeding toward . . . reduction to practice." *Id.*, 436 F.3d at 1382.

Tyco maintains that Ethicon's diligence argument fails because Ethicon's "redesign efforts" created a new "concept." However, as discussed *supra*, the Court rejects Plaintiff's contention that Ethicon has not proven prior conception because of its design changes. "If improvements caused loss of the original invention . . . the public would lose the benefit of diligent efforts to produce a more useful product." *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1333–34 (Fed. Cir. 2005) ("In this case, DX37, which

includes the same contested feature as DX34, represents an improved version of Wei's invention, not an entirely new invention.").

The evidence presented at trial clearly establishes "reasonable continuing activity" to reduce the invention to practice. Starting in 1996 and continuing well past Plaintiff's conception date, Ethicon kept weekly records of the progress of the UT5.5 team, as corroborated and testified to by Dr. Gallagher. (*See, e.g.*, DTXS 1383–1459.)

b) Lack of Abandonment, Suppression, or Concealment

Tyco also asserts that the conception/diligence § 102(g) defense must fail because Ethicon concealed its prior invention "by delaying its public disclosure." (Pl.'s Mot. at 25.) There are two types of abandonment, suppression, or concealment. *Dow Chem. Co. v. Astro–Valcour, Inc.*, 267 F.3d 1334, 1342 (Fed. Cir. 2001). "The first is implicated when an inventor actively abandons, suppresses, or conceals his invention from the public. . . . [and] [t]he second occurs when abandonment, suppression, or concealment may be inferred based upon the prior inventor's unreasonable delay in making the invention publicly known." *Id.*

Plaintiff's argument that Ethicon concealed its invention fails. The "critical timeline" for Defendant's § 102(g) defense is from a date just prior to Tyco's conception, i.e., January 1997, to Ethicon's date of reduction to practice. Ethicon filed its patent applications in October 1997, filed for FDA approval on January 9, 1998 and commercially launched the LCSB5 and K5 in August 1998.

"The failure to file a patent application, . . . to describe the invention in a published document, . . . or to use the invention publicly, . . . within a reasonable time after first making the invention may constitute abandonment, suppression, or concealment." *Dow Chem.*, 267 F.3d at 1342 (Fed. Cir. 2001) (internal citations omitted).

The Federal Circuit has cautioned that its "case law has not set strict time limits regarding the minimum or maximum periods between a prior inventor's first making of the invention and the subsequent disclosure of the invention necessary to establish or infer suppression, or concealment." *Id.* Indeed, the Federal Circuit has held that "a long delay between a prior inventor's first reduction to practice and subsequent filing of a patent application may be excused if the inventor worked during that period to improve or perfect the invention disclosed in the patent application." *Id.* at 1343 (citing *Lutzker v. Plet*, 843 F.2d 1364, 1367–68 (Fed. Cir. 1988)). In *Dow Chemical*, the Federal Circuit emphasized that:

> [D]uring the 30 months between first making the isobutene–blown foam and selling the foam, AVI actively and continuously took steps towards the commercialization of the foam, including the procurement of financing to build a new production plant and the attention to safety considerations associated with using isobutane as a blowing agent. A prior inventor is not required to take the fastest route to commercialization, but only to make "reasonable efforts to bring the invention to market." . . . Because the undisputed evidence shows that AVI made reasonable efforts towards commercialization, Dow has not shown, even prima facie, that AVI suppressed or concealed its invention.

Id. (internal citations omitted).

The record is devoid of any evidence that Ethicon "unreasonably delayed" the public disclosure of its invention once it had reduced its invention to practice: rather, Dr. Gallagher's testimony of the weekly reports of the team's efforts, starting in 1996 and going through 1998, corroborated by Ethicon's "historical summary" documents (*see* PQA, Wetlab Summary, UT 5.5 Hist. Summary [DTX 1538, 1539, 1540]), reveal work to "perfect the invention disclosed in the patent application." Further, because the operative time period is from January 1997 on, the trial evidence clearly established "reasonable efforts to bring the invention to market," and therefore, the Court finds that it is highly

probable that Ethicon did not abandon, suppress, or conceal its invention, and that accordingly, Ethicon has proven its § 102(g) defense.

However, as discussed *supra* in the fact finding section, the Court is persuaded that the prototype blades do not constitute invalidating prior art for the curved blade claims of the '286 and '544 patents. Accordingly, the Court finds that Ethicon has proved by clear and convincing evidence that only claims 1, 5, and 9–10 of the '050 patent, claims 1, 6, 7, and 8–14 of the '286 patent, and claims 1, 2, 9–13, 16, 18, and 23–25 of the '544 patent are anticipated by Ethicon's prototypes.

C. Obviousness and 35 U.S.C. § 103 Defense

"A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a).

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), [1] the Supreme Court explained:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin

[1] "He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office." *Graham v. John Deere Co. of Kansas City*, 383 U.S. at 19 (1966).

> of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

383 U.S. at 17–18.

The Supreme Court in *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S 398 (2007) recommended that a district court considering an obviousness defense look to: interrelated teachings of multiple patents, the effects of demands known to the design community or present in the marketplace, and any background knowledge possessed by a person having ordinary skill in the art, all in order to determine "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418.

At trial, Ethicon offered several arguments in favor of its obviousness defense: claiming that non–ultrasonic prior art is relevant to this analysis, and that in light of the Davison patent plus prior art, all of the asserted claims are rendered invalid on account of obviousness. For the reasons that follow, the Court finds that Ethicon has not met its burden of proof.

1. Obviousness Findings of Fact

a) Scope and Content of the Claimed Prior Art

In presenting his obviousness opinion, Dr. Cimino discussed devices, including non–ultrasonic devices, used in laparoscopic surgery—staplers, graspers, cutters, and dissectors. Dr. Cimino referenced the Davison '055 patent, the UltraCision and Ethicon prototypes, and four other specific patents as comprising the relevant prior art for his obviousness analysis: the Robinson '142 patent, the European Patent '315 ("EP '315), the

European Patent '662 ("EP '662"), and the Tovey '342 patent, four patents for non–ultrasonic devices used in laparoscopic surgical procedures.[13]

As an initial matter, the Court will not consider the UltraCision and Ethicon prototypes to be relevant "prior art" for the purposes of the obviousness analysis, as no convincing evidence was presented at trial that the prototypes and the drawings of the prototypes were "published" documents, and therefore they were not publicly available. Indeed, Dr. Cimino conceded that the sketches of the prototypes were all marked "Highly Confidential." (*See* 2012 Tr. at 1014–15.) Furthermore, as discussed above, Ethicon has not proved by clear and convincing evidence prior reduction to practice, and therefore, the prototypes cannot be considered "prior art" for an obviousness determination. *See Kimberly Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1445 (Fed. Cir. 1984) ("Proof of conception alone does to suffice to establish . . . work as prior [art].").[14] Lastly as

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[13] The full patent numbers for these four other prior–art references are: Patent No. 5,332,142 (Robinson); Patent No. 5,403,342 (Tovey); European Patent No. 0 503 662 A1 ("EP '662"); European Patent No. 0 640 315 A1 ("EP '315").

[14] Because the Court does not consider the prototypes to be prior art under § 103, Ethicon's Motion [Doc. # 213] to Strike the Testimony of Dr. Durfee that it would not be obvious to combine the teachings of the Davison patent with either the Ethicon or Ultracision prototypes because it would be "mechanically difficult to combine them" is denied as moot.

"[I]t is well–recognized that preclusion of expert testimony is a drastic remedy and should be exercised with discretion and caution." *Disability Advocates, Inc. v. Paterson*, No. 03-CV-3209 (NGG)(MDG), 2008 WL 5378365, at *12 (E.D.N.Y. Dec. 22, 2008). To the extent that Ethicon seeks to exclude all of Dr. Durfee's testimony about the mechanical difficulties of affixing the Davison curved blades disclosed in figures 8p and 8q, the Court will not disregard such testimony because it is relevant rebuttal testimony that was directly responsive to Dr. Cimino's testimony that the curved blades "taught" in Davison would have been obvious to one skilled in the art in 1997. The opinion offered by Dr. Cimino as to figures 8p and 8q was not in his expert reports, and therefore, to the extent any opinions expressed by Dr. Durfee were not fully disclosed in his expert report, they were responsive to Dr. Cimino's opinions in his expert report and testimony, and

discussed *supra*, Ethicon's patents were filed after U.S. Surgical/Tyco's patents were filed, and thus, they cannot qualify as prior art under § 103.

Dr. Cimino identified the Davison '055 patent, and three other, non–ultrasonic laparoscopic surgical instruments that he believed to be relevant to a § 103 analysis: the Robinson '142 patent [DTX 1170], which is a linear laparoscopic stapling device, EP '315 [DTX 1172], which is an electrosurgical and stapling device combined together, and the EP '662 [DTX 1171], a "laparoscopic jaw system that can be used for grasping, cutting, [and] dissecting" (2012 Tr. at 925). According to Dr. Cimino, each of the instruments, including the Davison '055 patent, has a handle so that the surgeon can open and shut the jaws, a "mechanical actuation system to transit down the shaft," (*id.* at 929:10–15), and the "common size for the laparoscopic instruments, and still remains today, are 5 and 10 mm devices" (*id.* at 929:15–19). He demonstrated that "they all have a shaft that goes

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were based upon the same information and data relied upon by Dr. Cimino to formulate those opinions. *See New York v. Solvent Chem. Co., Inc.*, 685 F. Supp. 2d 357, 416 (W.D.N.Y. 2010) *aff'd in part, vacated in part on other grounds*, 453 F. App'x 42 (2d Cir. 2011) ("[T]he court's review of the trial testimony indicates that the areas covered by Mr. Hall during both direct and cross–examination were the same topics covered by Mr. Smyth during his testimony, and Solvent had ample opportunity to explore the basis for Mr. Hall's rebuttal testimony during . . . cross–examination."). The court in *Solvent Chem.*, considering a motion to strike an expert's testimony on similar facts as those at issue here, held:

> Based on this review of the record, the court finds that to the extent any opinions expressed by [expert] Mr. Hall at trial were not fully disclosed in his expert report, such testimony was offered by Olin to rebut the opinions expressed by Mr. Smyth in his expert report and testimony, and was based upon the same information and data relied upon by Mr. Smyth to formulate those opinions. Solvent had a full and fair opportunity at trial to explore the basis for Mr. Hall's opinions, without the need for a continuance. Accordingly, any failure on the part of Olin to supplement Mr. Hall's expert report was harmless, and there is no other basis for finding that Solvent was prejudiced by Mr. Hall's trial testimony.

685 F. Supp. 2d at 416.

through a trocar, whether that be 10 or 5mm, . . . [a]nd they all have end effectors or something to grasp or grab or cut or staple tissue on the end." (*Id.* at 930:3–5.)

Dr. Cimino opined that ultrasonic and laparoscopic surgical instruments also transmit energy or mechanical motion from the handle to the jaws with "two common approaches": "[t]here's a solid rod, or bar, that is used to transmit the forces, or it can be a tube. Both of these are commonly known[;] it's one or the other." (*Id.* at 930:9–12.) He further opined:

> With regard to the mechanism to open and shut the jaws, there are three common mechanisms that are used: A rod linkage mechanism, which puts a solid rod back and forth; or a gear rack mechanism, as I've already discussed previously; or a cam mechanism. These are the three common mechanisms used to open and shut jaws.
>
> [The] Rotation knob shown in the device, is used so that the surgeon can rotate whatever is on the end of the device into a better position for him to perform surgery. And the concept of rotating is included in almost every laparoscopic instrument to rotate the jaw, or whatever they want to rotate, on the end.

(*Id.* at 930:13–931:1.)

b) Ultrasonic Device: Davison '055

The Davison '055 patent, dated June 21, 1994, discloses an ultrasonic laparoscopic surgical instrument having

> a handpiece with a transducer for converting an electrical signal into longitudinal vibratory motion of a blade connected to the handpiece and an accessory releasably connected to the handpiece to enable clamping of tissue against the vibrating blade to afford improved coagulating and cutting of tissue. Scissors–like grips actuate a pivoted clamp jaw along one side of the ultrasonically vibrating blade to compress and bias tissue against the blade in a direction of longitudinal vibratory movement. The clamp jaw and blade are rotatable relative to one another to align a selected blade edge of a multi–edged blade with the clamp jaw for cutting and coagulating while clamping or circumferentially spacing a selected

> blade edge from the clamp jaw for cutting and coagulating without clamping.

(Davison '055 Patent Abstract [DTX 1169].) The Davison '055 patent has housing, a handle, an elongated tube, a vibration coupler, blade, options for a curved blade and curved blade surface, a jaw clamp, clamping surface, a removable transducer, vibrating and sealing rings, a tissue stop, an actuation rod, a pair of pivot pins, and a rotation knob. (*See* '055 patent, Fig. 1a.) Davison is a 10mm ultrasonic surgical instrument, and the Court finds that the Davison patent constitutes relevant prior art under § 103.

c) Laparoscopic, Non–Ultrasonic Devices

Dr. Cimino also identified other relevant prior art that informed his obviousness opinion, including EP '315 which was filed in 1994 and discloses an actuator tube–in–tube design, a cam mechanism to open and close the jaws, a rotation knob, and tissue stops.

Dr. Cimino relied on the Robinson '142 patent, which is a "linear stapling mechanism with cutting means," that uses an actuator tube (tube–in–tube design), a cam mechanism to open and close the jaws, a rotation knob to rotate the jaws, and includes a coupling and swivel member combination.

He mentioned the Tovey '342 patent [DTX 1167], an "articulated endoscopic surgical apparatus," which is a laparosopic instrument with a handle, a shaft, and rotation, and he concluded that "the inventors of this patent were very familiar with the concept of rotation, handles of laparoscopic instruments." (2012 Tr. at 949:14–16.)

Dr. Cimino also pointed to EP '662 as a relevant prior art device, an "approximating apparatus for surgical jaw structure," that has a jaw closure system that can be used for gripping, grasping, dissecting, cutting, measuring, stapling, etc. (*See* DTX

1171, "Summary of the Invention.") This invention, filed in 1992, has a pair of camming members, camming slots, and discloses an actuator tube within a tube design. Dr. Cimino then concluded that in his opinion, claims 1, 5, and 9–12 of the '050 patent were obvious in light of a combination of elements from Davison, Robinson '142, and EP '662; claims 1, 6–15 of the '286 patent were obvious in light of a combination of elements from Davison, Robinson '142, EP '315, and EP '662; and claims 1, 2, 3, 6, 8, 9, 10, 11, 12, 13, 16, 18, and 23–25 of the '544 patent were obvious in light of a combination of elements from the same prior art devices. (2012 Tr. at 967; *see also* Cimino Presentation [DTX 2437].)

d) Differences Between the Claimed Invention and the Prior Art

On cross–examination, Dr. Cimino clarified that the electrosurgical devices used in laparoscopic surgery that he found to be relevant "prior art" use electrical energy flowing in the device, and that, unlike in ultrasonic devices, there are no vibrations in the shaft of those devices. (2012 Tr. at 993.) Gary Whipple, one of Ethicon's mechanical design engineers and co–inventors of the prototypes, acknowledged in his deposition testimony that "existing laparoscopic instruments" were "not a whole lot of help" when he was trying to invent the 5–mm ultrasonic device. (2007 Tr. at 1379:25–1380:6.) When asked about this portion of Mr. Whipple's testimony, Dr. Cimino opined that "is it is my position and my belief that laparoscopic instruments as a whole are things that not only I'm familiar with, but that they are out there and they contain many relevant mechanisms and things that could be useful in the design of a 5 mm device." (2012 Tr. at 1020:8–13.)

As to the non–ultrasonic, laparoscopic references, Dr. Durfee found Dr. Cimino's reliance on these non–ultrasonic devices as prior art problematic with respect to the patented features, because "none of these prior arts have to do with . . . the absolutely

critical part of an ultrasound instrument which is that vibration coupler or vibration rod that has got to run end to end of the instrument and has got to be straight and unbroken and has got to be isolated from other components." (*Id.* at 1794:3–10.) He further opined that the issue of the vibration rod

> [is] absolutely essential for an ultrasound instrument, and staplers and electrosurgical instruments and graspers and cutters don't have to handle that issue. So, therefore, these prior art cites wouldn't be particularly useful in solving the specific problems that Davison has in terms of getting Davison to certain of the claimed features of the patents.

(*Id.* at 1794:11–18.)

Tyco points to a section of the reexamination history for the Davison '055 patent [PTX 480] as evidence that Ethicon itself took the position that ultrasonic technology was separate from non–ultrasonic laparoscopic technology. There, Ethicon distinguished the Davison technology from the Ferzli reference—a mechanical device "which does not employ ultrasonic energy and relies instead on purely mechanical elements for grasping and cutting" ('055 Reexamination at 26), and "describes a device which is substantially different in the structure and function from either the device described in . . . Applicant's claimed invention" (*id.* at 27). Ethicon concluded that "it was inappropriate to rely upon Ferzli as a reference in rejecting Applicant's claims under 35 U.S.C. 103 since that reference represents non–analogous art and Applicant respectfully requests that the Examiner's rejection based upon Ferzli be withdrawn." (*Id.* at 27–28.) Ethicon responds with Dr. Cimino's testimony that "[i]f I'm only concerned about the ultrasonic portion, I would be looking at ultrasonic . . . devices. . . . I would not look [at mechanical devices] first probably." (2012 Tr. at 1035–36.)

2. Discussion and 35 U.S.C. § 103 Conclusions of Law

Obviousness, like a defense under § 102(g), requires proof by clear and convincing evidence. "To render a claim obvious, prior art cannot be "vague" and must collectively, although not explicitly, guide an artisan of ordinary skill towards a particular solution." *Unigene Laboratories, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) *cert. denied*, 132 S. Ct. 1755 (2012) (internal citation omitted) "[M]ost inventions that are obvious were also obvious to try," *id.*, "and a combination is only obvious to try if a person of ordinary skill has 'a good reason to pursue the known options.'" *id.* (citing *KSR*, 550 U.S. at 421). "[W]hen prior art gives 'no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful,' an invention is not obvious to try." *Id.* (citing *Bayer Schering*, 575 F.3d at 1347); *Ortho–McNeil*, 520 F.3d at 1364 (stating the number of options must be "small or easily traversed").

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR*, 550 U.S. at 417. The question therefore, is whether, the attributes of the Davison '055 patent, plus the non–ultrasonic laparoscopic references cited by Dr. Cimino, would yield a predictable variation, as argued by Ethicon, or whether Tyco's patents brought something "unexpected" to the field of ultrasonic technology.

Ethicon's obviousness case is based on the argument that if one looked around at non–ultrasonic, laparoscopic surgical devices in addition to the Davison '055 patent, elements of each of the patented features existed in prior inventions, and therefore, a combination of the elements in just such a way as the '050, '286, and '544 patents would

have been obvious. Though the simplicity of this argument seems tempting, this is insufficient to make a clear and convincing case that the patents in suit "only unite[] old elements with no change in their respective functions." *KSR*, 55 U.S. at 415 (citing *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152–53 (1950)).

As discussed below, the Court is not persuaded that Ethicon has done more than point to many elements from other devices, which pasted together could have yielded something like the patents, but fails to connect the dots as to why an engineer of ordinary skill would have seen a benefit to using curved blades, dual cam mechanisms, creating a device that fits down a 5mm trocar, rotation of the blade and clamp, and the use of the tube–in–tube design. As the Supreme Court described in *KSR*, "[t]he fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that [the inventor's] design was not obvious to those skilled in the art." 550 U.S. at 416.

a) Davison '055 Patent

While a person of ordinary skill in the art would have looked to Davison when inventing an ultrasonic cutting and coagulating device that would fit down a 5mm trocar, Defendant has not shown that the path from Davison to all of the asserted claims of the '050, '286, and '544 patents is "commonsensical."

(1) Curved Blade Claims (Claim 15 of the '286 Patent; Claims 6, 8 of the '544 Patent)

When asked specifically about curved blades, Dr. Cimino pointed to figure 8p, which "is obviously a curved blade surface" (2012 Tr. at 920:16–17), and that therefore, claim 15 of the '286 patent and claims 6 and 8 of the '544 patent would have been obvious in light of the Davison '055 patent. (*Id.* at 923:17–19 ("[T]he Davison ultrasonic

instrument clearly shows curved blade surfaces, curved blades, as using the constructions of the Court.").)[15]

In response, Dr. Durfee highlighted the fact that the Davison patent's preferred embodiment teaches away from a curved blade. (*See id.* at 1827.) Thus, even if Davison '055 shows two figures of curved blades (*see* '055 patent, Figs. 8p, 8q), the patent itself generally teaches a straight blade. For example, of all of the blade designs illustrated "for use with the ultrasonic surgical apparatus" ('055 patent at Col. 12. 12–13), only two of fifteen blade designs show curved blades (*see id.* Figs. 8a–8o). Further, figures 8p and 8q are presented as exceptions, to facilitate "treatment of tissue at awkward angles of approach" (*see id.* at Col. 13.23–24 (describing Fig. 8p)), or "*different* angles of approach" (*id.* at Col. 13:27–28 (emphasis added)).

Dr. Durfee also noted that the curved blades depicted in Davison would not have been "obvious" to one skilled in the art in 1997. Looking specifically at figures 8p and 8q of the Davison '055 patent, Dr. Durfee emphasized that "Davison in its preferred embodiment teaches a straight blade. . . . There [are] maybe a dozen figures of possibilities for blades, but they're not the way that Davison teaches how to do its preferred blade." (2012 Tr. at 1760–61.) Dr. Durfee pointed out that, as to 8p and q:

> One of the things to remember about the claim is it's a dependent claim and the claim it is dependent upon requires a clamp. So, in order to get the curved blade, you need to have a clamp. Well, 8q has no clamp in the figure. It's just doesn't say how to do the clamp. 8p, up on top, has what appears to be a clamp, which is indicated at 24p, but the people who wrote that patent don't show you how that clamp opens and closes, it just kind of sits there floating in midair. It's got something on the proximal end of 24p

[15] Dr. Cimino also pointed to figure 8g of the Davison '055 patent, which depicts a circular cross–section of a blade. However, as addressed *supra*, the Court concludes that a circular cross–section did not meet the requirements for a curved blade surface as disclosed in the '286 and '544 patents.

> that might be a pivot point, but if you were to pivot the clamp around that point it would touch down only at its tip so it wouldn't be a particularly useful clamp.

(*Id.* at 1761:10–24.)

Thus, the Court concludes that Ethicon has not proven that is it highly probable that one of ordinary skill in the art reading the Davison '055 patent would have considered curved blades to be generally desirable. *See Unigene Labs*, 655 F.3d at 1363 ("In fact, the #315 patent teaches away from using about 20 mM citric acid as an absorption enhancing agent or stabilizing agent . . . . One of ordinary skill the in art reading the #315 and #116 patents would have considered about 20mM citric acid *undesirable* in a liquid nasal formulation containing salmon calcitonin." (emphasis added)).

Further, even if one of ordinary skill in the art were to be motivated to use curved blades generally, and not just as specified in the Davison '055 for "awkward" angles of approach, the Davison '055 patent provides no guidance for how one would affix such a curved blade to the clamp arm.[16] As noted by Dr. Durfee, the asserted curved blade claims of both the '286 and '544 patents are all dependent claims: claim 15 of the '286 patent depends on claim 7, which requires a "cutting jaw having a cutting surface . . . with a clamp member supported adjacent to cutting jaw, the clamp member and the cutting jaw defining a tissue receiving area," with claim 15 requiring "the cutting surface of cutting jaw curved along the longitudinal axis of the instrument"; and claims 6 and 8 of the '544

[16] Tyco's argument that if a curved blade was so "obvious," it is curious as to why it took Ethicon's own engineers nearly seven years between the filing of the Davison '055 patent and the launching of their own curved shears products, is supported by Mr. Bishop's testimony in 2007: "A curved blade is more difficult to do than a straight blade." (2007 Tr. at 583.)

patent are dependent on claim 1, which requires a "clamp member movable in relation to the jaw member between open and clamped positions," with claim 6 specifying that the "jaw member includes a curved blade surface." It appears, therefore, that given the dependence of the asserted curved blade claims on other independent claims, it is not highly probable that it would have been obvious for one skilled in the art to implement curved blades as specified in the patents in suit simply based on the drawings of curved blades in the Davison '055. *Cf. In re Cyclobenzaprine*, 676 F.3d 1063, 1073 (Fed. Cir. 2012) ("[W]here the prior art, at best, [gives] only general guidance as to the particular form of the claimed invention or how to achieve it, relying on an 'obvious–to–try' theory to support an obviousness finding is 'impermissible.'") (internal citations omitted).

Finally, the Patent and Trademark Office considered the Davison '055 in the prosecution of the curved blades claims of the '286 and '544 patents and permitted the claims. In its patent applications, United States Surgical Corp. ("USSC") distinguished the Davison '055 patent as follows:

> [Davison] discloses an ultrasonic surgical instrument adapted for endoscopic use having a blade and a clamp movable in relation to the blade to capture tissue therebetween. The blade and the clamp define a clamping region having a plane which is parallel to the longitudinal axis of the surgical instrument. During an endoscopic procedure, movement of the instrument is limited to movement along an axis parallel to the plane of the clamping region. Thus, no additional blade force is imposed on the body tissue as a result of movement of the instrument.
>
> Accordingly, a need exists for an improved ultrasonic surgical instrument which is easy to use and provides fast and easy cutting and improved coagulations.

('286 Patent at Col. 1.40–53; '544 Patent at Col. 1.41–51.)

That Tyco's patents disclose a method of affixing curved blade surfaces onto clamp members movable in relation to that curved blade, while the Davison '055 merely

shows two images of curved blades that can be used for "awkward angles of approach" reveals to the Court a lack of obviousness—where Tyco's inventions were able to assemble these elements in an "unexpected and fruitful manner." 550 U.S. at 416. Thus, the Court finds that the curved blade claims of the '286 and '544 patents were not obvious in light of the Davison '055 patent.

(2) Camming Claims (Claims 11, 12 of the '050 Patent; Claims 8–14 of the '286 Patent; Claims 1, 2, 3 of the '544 Patent)[17]

The Davison '055 patent does not disclose a camming mechanism to open and close the clamp. Dr. Cimino's opinion that using a cam mechanism would be obvious given that a cam is one of three mechanical options to choose from does not explain why it would be highly probable for someone of ordinary skill in the art to select a cam mechanism, when presented with the other options before him or her. "[I]n the determination of obviousness, there must be factual support for an expert's conclusory opinion." *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000). Based on this evidence, the Court does not find the camming claims obvious.

As to the dual cam claims, Ethicon relies on the "contemporaneous invention" of the UltraCision and Ethicon prototypes, and argues that it would have been obvious in light of the prototypes to switch to a dual cam design, thus rendering claims 11 and 12 of the '050 patent invalid.

The Court disagrees. Dr. Durfee convincingly testified that while it might sound simple, or "obvious" to "just split this cam right down the middle . . . that's not going to

[17] Ethicon's Motion for Judgment as a Matter of Law [Doc. # 210] does not address the obviousness of all of the camming features in suit, but focuses only on the dual cam claims (claims 11 and 12 of the '050 patent, and claim 3 of the '544 patent). Nonetheless, the Court addresses the obviousness defense with respect to all cam claims.

be a good way to give yourself a working dual cam mechanism." (2012 Tr. at 1768:7–11.) Dr. Durfee also pointed out the "considerable design history" on Ethicon's part (*see* DTX 1568)—that Ethicon was working "to figure out how to go from the single tabbed design to something else that the UltraCision team undertook" (*id.* at 1770–21) and that the dual cam design was clearly not "obvious" to them. Ethicon has not convinced the Court that one of ordinary skill in the art in 1997 would have "had a reason to select the route that produced the claimed invention." *In re Cyclobenzaprine Hydrochloric Extended–Release Capsule Patent*, 676 F.3d 1063, 1073 (Fed. Cir. 2012), *cert. denied*, 12-514, 2013 WL 141183 (U.S. Jan. 14, 2013).

Further, though Dr. Cimino testified that the difference between a single "cam" or dual cams was insignificant, and would therefore be obvious, Dr. Durfee opined that it was far from insignificant, and that it was in fact helpful in reducing the device to a 5mm size:

> The dual cam mechanism, particularly as it's shown in the patents and also shown in the accused products, by having the dual cams both on the sides in the way that they're structured to maintain the strength, that's in both cases a very effective way of being able to miniaturize the device down to 5 mm and still get significant clamping forces.

(2012 Tr. at 1796:7–14.) Thus, rather than being obvious or insignificant, Dr. Durfee's testimony shows that the choice of dual cams revealed a "fruitful" decision that aided in shrinking the device down in size, as compared to Davison's 10mm device. Thus, the Court does not find the dual cam claims to have been obvious in light of the prior art.

(3) Tube–in–Tube Design (1, 5, 9–12 of the '050 Patent; Claims 8–14 of the '286 Patent)

The Davison '055 patent does not teach a tube–in–tube construction. Indeed, it specifically discloses an actuation member. Dr. Cimino pointed out that the '050 patent

itself discloses both actuation by "rod" and actuation by "tube" (see '050 patent, Figs. 3, 20), that is, "two of the three most common mechanisms to open and shut a jaw" (2012 Tr. at 939:8–9.) This, testimony however, does not address why, simply because one of Plaintiff's patents discloses both manners of actuation, that it would have been obvious to one of skill in the art at the time, as opposed to being the product of inventor innovation.

(4) Rotation (Claims 1, 5, 9–12 of the '050 Patent; Claims 1, 6, 12–13 of the '286 Patent, and Claims 10–12 of the '544 Patent)

As to the rotation of the blade and clamp together, Dr. Durfee pointed out that the Davison '55 patent "very clearly calls out the advantages of rotating the blade only." (2012 Tr. at 1797:22–23; *see also* Davison '055 Col. 3.20–25.) Dr. Cimino conceded that the Davison '055 patent does not specifically describe rotation of the blade and the clamp member, but that the other references that he considered all provide rotation of the jaw mechanism "and everything else." (2012 Tr. at 940.) Thus, the Davison '055 patent does not render the rotation claims obvious.

(5) Tissue Stops on the Clamp ('050 Patent; Claims 6–14 of the '286 Patent; Claims 23–24 of the '544 Patent)

Dr. Cimino only opined, without further factual support, that it would be "obvious" to move the tissue stops to the clamp arm, rather than on the tube, as the Davison '055 patent teaches, and that the difference between tissue stops at the back of the clamp, as disclosed in the Davison '055 patent, and having the tissue stops present on the jaw was "insubstantial" (*id.* at 943). Dr. Cimino also disagreed with Dr. Durfee that the transducer in Davison '055 is not removably attached to the housing. (*See id.* at 943:8–11.)

However, this conclusion fails to explain why one of ordinary skill would have been motivated to move the tissue stops to the clamp arm. "[A] combination is only obvious to try if a person of ordinary skill has 'a good reason to pursue the known options.'" *Unigene*, 655 F.3d at 1361 (citing *KSR*, 550 U.S. at 421). Dr. Cimino's conclusory opinion that it would have been obvious to try placing the tissue clamps on the jaw in light of the Davison '055 patent does not explain why one would have a reason to do so, and thus, the Court does not find this claim to be obvious.

(6) Use in a 5mm Trocar (Claim 18 of the '544 Patent)

Only Claim 18 of the '544 patent requires that the invention fit down a 5mm trocar. While Dr. Cimino testified that "miniaturization" of the Davison 10mm device would be obvious, the parties' experts both agree that there is no disclosure in the Davison '055 patent of how its invention could fit down a 5mm trocar. (2012 Tr. 1789:20–22.) Dr. Cimino opined that "there is nothing inherent in the Davison patent that could not be reduced to a 5 mm size." (*Id.* at 940:7–9.)[18]

However, on cross–examination, Dr. Cimino conceded that when Ultracision and Ethicon were working on developing their own 5mm device, they rejected the actuation rod mechanism of the type disclosed in the Davison '055 patent and instead used a tube–within–tube design. (*Id.* at 984.) Further, Dr. Davison himself, at the 2007 portion of the trial, admitted that even though there was a preference for a 5mm device in 1993 when he

[18] Dr. Cimino also opined that it is not necessary to use a tube–in–a–tube design in order to create a device that fits within a 5 mm trocar (2012 Tr. at 940), citing to the Olympus Sonosurg [DTX 1080] instrument as evidence of a "device that is a 5 mm ultrasonic and laparoscopic .and does not even use a cam mechanism to open an shut the jaws" (*id.* at 942:13–16). However, Ethicon did not present evidence that the Sonosurg is, or should be treated as, relevant prior art for § 103 purposes. Thus, the Court finds that the Sonosurg device is not within the scope and content of prior art for the purposes of its § 103 analysis.

developed and launched the LCS 10 device there were concerns that "bringing it down to 5mm" would create additional technical risks, and "[y]ou need to walk before you run." (*See* 2007 Tr. at 1327:12–24.)

Dr. Durfee testified that if one were to merely "shrink down" the Davison design, there would be fundamental functional issues with the device: "you are going to have problems getting equal clamping force because that distance between where the rod comes into the clamp and pivot point is smaller" (*id.* at 1791:3–6), and "the clamp is going to be very sensitive to handle motion" (*id.* at 1791:10–11). He concluded that given Davison's configuration, "it's not going to be straightforward. It's going to take considerable mechanical challenge to get it to shrink down while still having an effective clamp." (*Id.* at 1792.) U.S. Surgical Inventor Dominick Mastri echoed this testimony in his testimony at the 2007 trial phase, recalling that "structurally, it was impossible to run things down the center of the device because of the reduced size, . . . [c]losing the clamp down to fit into a 5–millimeter device also became a challenge, and how to actuate it really was a difficult thing to develop." (2007 Tr. at 127; *see also* 2012 Tr. at 382 (Dr. Gallagher: "[T]here wasn't an appreciation of the complexity of decreasing the size of the shears.").)

In the face of all the testimony offered about the difficulty in working with a reduced size, the Court finds that while the evidence shows it may have been desirable to work towards the creation of an ultrasonic instrument that fits down a 5mm trocar, the Davison '055 patent does not render claim 18 of the '544 patent obvious.

b) Non–Ultrasonic Prior Art

As discussed above, Dr. Cimino opined that in 1997, one skilled in the art would have looked to non–ultrasonic instruments in attempting to solve the issues that Tyco's

own inventors were trying to solve, namely, "issues of mechanical opening and shutting jaws, [and] transmitting forces up and down shafts" (2012 Tr. at 968), and that these inquiries are not unique to ultrasonic instruments.

"Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination." *Unigene Labs.*, 655 F.3d at 1360 (citing *KSR*, 550 U.S. at 418). While Ethicon has pointed to elements of the non–ultrasonic laparoscopic surgical instruments that have camming members, rotatability of the blade and clamp arm, tube–in–tube designs, and the ability to fit down a 5mm trocar, the fact that such elements existed out in the laparoscopic surgical world is not enough to render them invalidating prior art on account of obviousness. As discussed *supra*, Drs. Durfee and Cimino disagreed on the key issues of whether a person of ordinary skill in the art would consider it fruitful to look to the Robinson patent, the EP '315, the EP '662, or the Tovey patent, given the specific challenge of fitting the vibration coupler or rod along the length of an ultrasonic instrument, while also including the other asserted patented design elements.

Accordingly, the Court finds that Ethicon has not met its burden of proving any of the asserted claims obvious in light of a combination of the Davison '055 with the Robinson patent, the EP '315, the EP '662, or the Tovey patent, and finds that Ethicon has not proven obviousness by clear and convincing evidence as to the asserted claims.

V. Damages

Based on the findings of fact and conclusions of law discussed above, the Court concludes that the only claims that remain valid, and therefore entitled to any damages award, are claims 11 and 12 of the '050 patent, claim 15 of the '286 patent, and claims 3, 6, and 8 of the '544 patent.

The parties have stipulated that if damages are to be awarded, Tyco would only be entitled to a reasonable royalty from April 1, 2004 to January 14, 2010. From January 14, 2010 to the present, Tyco asserts that it is entitled to damages for lost profits and royalty damages.[19] The Court will first address Tyco's lost profits case and then the reasonable royalty rate.

A. Entire Market Value Rule

Ethicon objected in closing arguments and post–trial briefing to the Plaintiff's calculation of damages based on the entire value of the patented products. The Federal Circuit describes the "entire market value" rule as a means of calculating damages "to include in the compensation base unpatented components of a device when the unpatented and patented components are physically part of the same machine." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549 (Fed. Cir. 1995) (en banc). "[T]he Rite-Hite 'functional unit' test set forth the key criterion for lost profits of unpatented materials used with a patented device." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 382 F.3d 1367, 1372 (Fed. Cir. 2004) (citing *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1361 (Fed.Cir.1999) (affirming a jury award of damages based on the entire market value rule and the functional relationship between patented fans and unpatented radiator and condenser assemblies)).

Here, it is undisputed that the patented features of the accused devices—the curved blade and dual camming mechanisms—are physically connected and part of the accused devices. In addition, Defendant's damages expert Dr. Gregory Bell uses the entire market value of the accused products in his own damages calculations. Thus, and without

[19] The expert's damages calculations only account for damages through March 31, 2012. Dr. Ugone has offered to provide the Court with updated figures at the Court's request.

the benefit of consideration of an alternative from Defendant, the Court will consider the entire market value of the devices in its damages analysis.

B. Lost Profits

Tyco asserts that it is entitled to lost profit damages from January 14, 2010 to the present. To prove lost profits on sales he would have made absent the infringement, i.e., the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) causation to lost sales, by showing the absence of non–infringing substitutes or by showing patentee's established market share, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978); *State Indus., Inc. v. Mor–Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989).

1. Demand for the Patented Products

The first *Panduit* factor does not require any allocation of consumer demand among the various limitations recited in a patent claim. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331 (Fed. Cir. 2009) ("[T]he focus on particular features corresponding to individual claim limitations is unnecessary when considering whether demand exists for a patented product under the first Panduit factor."). Instead, it "simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.'" *Depuy Spine*, 567 F.3d at 1330 (citing *Rite-Hite Corp.*, 56 F.3d at 1548–49).

The Court finds that Tyco has proved by a preponderance of the evidence that the demand existed for the features covered by the '050, '286, and '544 patents—that is, curved blades, rotation, and the ability to fit down a 5–millimeter trocar. As discussed *supra*, the Court finds that the rotation and 5mm claims are invalid because Ethicon has

proved its § 102(g) defense by clear and convincing evidence. Though the Court also finds it likely that consumer demand existed for all three of those patented features, given the invalidity conclusions, the Court focuses its analysis here on the curved blade feature as a driver of demand.

While the issue is a close one, Tyco has provided a record replete with items of evidence showing that consumers valued the curved blades (see Harmonic Scalpel, the Precise Instrument, Account Specialist Training [DTX 1674] at EES0161520–543 at 522, 529 (A General Surgeon stated, "[b]ig difference between the curved and 5mm!" and "[b]etter visibility—curve design—makes it easier to see tip around structures, and a GYN Surgeon stated "[c]urved design offers a better angle of approach," and "the curved LCS is more versatile than the 5mm LCS.")), and Ethicon's own marketing documents reflecting that they were aiming to "meet market demand for curved shears." (DTX 1859 at EEOS0161609.) Mr. Karim Khadr, former Director of Global Product Development at Ethicon, testified at his deposition that "the curved design offered better visibility at the surgical site" (Khadr Dep. at 53–54), and opined that "the curved may have been the unmet need for the surgeon or it could have been something related to hemostasis or speed, which the curve also delivers on, relative to the straight" (*id.* at 41–42).[20]

Ethicon challenges Tyco's argument that there was demand for the curved blade, pointing to several other surgeons' statements showing a lack of enthusiasm for that feature. For instance, in "Harmonic Scalpel—Value Points," Competitive Analysis and

[20] Arguing that the curved blade claims cannot be used to satisfy the first *Panduit* factor, Dr. Bell, Ethicon's damages expert, points out that the Autosonix, Tyco's own 5 millimeter ultrasonic harmonic scalpel instrument, does not have a curved blade. While interesting, it is not relevant to the Court's damages analysis, which must focus on whether Ethicon's infringing products "directly compete" with Plaintiff's patented devices. *See Rite–Hite*, at 56 F.3d at 1548–49 (accused products themselves are the only focus of the 'demand' inquiry under *Panduit*'s first prong).

Strategic Price Setting [DTX 1828], a physician stated that "he does not have a need for a curved shear"; another stated that there was "no difference" between the Harmonic Scalpel's curved shear and the SonoSurg's straight blade, and that "anyone who would tell you that there is a difference in visibility due to a 15–degree curve in the blade is kidding themselves" (*id.* at EES0266414). However, while there may have may have been additional drivers of demand for the accused products, the evidence presented at trial shows that the curved blade was sufficiently important to Ethicon that it included the "curved" aspect of its shears in its marketing materials and in its devices' name (i.e., "*curved* shears"), and that, for the narrow purpose of meeting *Panduit*'s first prong, Tyco has met its burden of showing demand for the patented products.

2. Causation to Lost Sales

As to *Panduit*'s second factor—causation to lost sales—a plaintiff must show a linkage between Ethicon's infringing activity and Tyco's lost sales, and that "but for" the infringement, there was a reasonable probability that the sales would have gone to Tyco. *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1360 (Fed. Cir. 2012) (citing *Rite–Hite*, 56 F.3d at 1545). There are two means by which a party can establish causation: first, under *Panduit*, a party could show that the infringer had no non–infringing substitute products which could have permitted it to retain its customers, *see Panduit*, 572 F.2d at 1156, or second, under *Mor–Flo Industries, Inc.*, 883 F.2d at 1152, by establishing the market share allocation that Tyco would have had were it not for Ethicon's infringing products. Tyco has asserted a market share allocation approach to prove causation. As discussed *infra*, the Court finds that Tyco has not met the requisite burden of proof to show causation to lost sales.

The parties' experts disagree on how to reconstruct the market for the purpose of this analysis. Tyco's damages expert, Dr. Keith Ugone, described the market as one of "5 mm advanced energy–based cutting and coagulating devices." (2012 Tr. at 1058:21–22.) He testified that Tyco has several products which compete in this specific market: (1) the AutoSonix Ultra Shears product, which is a device using ultrasonic energy, and (2) the LigaSure line of products, which are "advanced bipolar," or "radiofrequency" ("RF") devices. (*Id.* at 1062.)

Indeed, the evidence presented at trial shows that Tyco's and Ethicon's advanced energy products directly competed with each other. Tyco's Senior Director of Global New Product Energy Development Philip Roy testified that since he started working at Tyco in the late 1990s, the advanced energy market "is fairly concentrated between us and Ethicon, the Harmonic being the larger market share player" (2012 Tr. at 117:5–7), and that throughout his career, "we've had direct competition between these devices" (*id.* at 117:20–21). Ethicon's own marketing materials described the Autosonix device as a direct competitor with its own LCS devices (*see, e.g.*, Account Specialist Training [DTX 1858]; PTX 41 at EEOS0264002; PTX 47). In fact, both parties' experts, Dr. Ugone and Dr. Gregory Bell for Ethicon, agree that the AutoSonix device competes with the Harmonic Shears.

With regard to the LigaSure devices, Defendant's marketing and research and development materials suggest that Ethicon also considered the LigaSure—Tyco's bipolar energy cutting and coagulating device—to be a competitor. (*See* August 2008 Awareness, Trial and Usage [PTX 582] (identifying the LigaSure as one of among the "key Harmonic competitors").) Though Ethicon's witnesses testified at trial that the RF energy products and the ultrasonic products were really separate markets, the evidence all suggested that

while the RF products may have had an edge in terms of sealing capacity, while the ultrasonic instruments had an edge in cutting capability, Tyco and Ethicon's witnesses agreed that both types of energies could be used for the same surgeries, corroborating Dr. Ugone's view that the devices can function interchangeably. (*See, e.g.*, Bell Testimony, 2012 Tr. at 1540; Roy Testimony, *id.* at 155–56.)[21]

The market reconstruction painted by Dr. Bell looked markedly different, because he created his view of market allocation by essentially creating two separate markets: the market for devices that seal vessels of 3mm or less, and the market for devices that seal vessels of 3mm and more. In his version of the "but for" world, that is, a world without the infringing products, the "immune" B and K products[22] would fill in the 'hole' created in the market by the removal of the infringing devices. The result of dividing the markets in such a way is that Ethicon's infringing devices, which are replaced by the B and K products, take up a larger portion of the "less than" 3mm vessel–sealing market, while Tyco's RF devices comprise a larger portion of the "greater than" 3mm vessel–sealing market.

Dr. Bell also opined that "short units" of less than 24 cm in length and "long units" of 45 cm should be removed from the market reconstruction, because the "short units" are only used in open procedures, and Tyco does not have a substitute for the "long

[21] There was also evidence that Ethicon purchased EnSeal to develop its own market share in terms of RF devices. While this evidence could suggest that EnSeal and LigaSure competed within their own market, separate from ultrasonics, based on six Energy Insight surveys conducted by Ethicon, it appears that of the surgeons who shifted to Enseal devices, between thirty to fifty percent of them were shifting from Harmonic products, i.e., ultrasonic energy devices, to the EnSeal device. (2012 Tr. at 1086; *see also* PTXS 508, 580, 579, DTXS 2045, 2046, 2044.).

[22] The "immune" products are those identified in a 1999 Settlement Agreement between Tyco and Ethicon, which also includes Plaintiff's AutoSonix product.

units." (*See* Ex. H-3 to Bell Expert Report [DTX 2427].) However, as to the "long units," Tyco sells a LigaSure product that is 37 cm long, which Dr. Bell conceded was a length that is used specifically for bariatric surgeries for the "morbidly obese." (2012 Tr. at 1597–98.) Dr. Bell does not explain what, in particular, makes the 45 cm length exclusive, and he conceded on cross–examination that Tyco's 38.5 cm (Autosonix) and 37 cm (LigaSure) devices competed against a 45 cm product. (2012 Tr. at 1601; *see also* "Project Scope" [DTX 2251] at EEOS 191022 (noting that Tyco's 38.5 cm–long device, among other longer devices in the market "drove [Ethicon's] criteria for 44cm length.").)

As to the 24 cm "short unit" devices, Dr. Bell further conceded on cross examination that he did not consider whether, and to what extent, "short unit" devices could be used in pediatric laparoscopic surgery, but testified that he agreed that sales of "the ones used pediatrically" should be factored back in. (2012 Tr. at 1596.) Given this evidence, the Court does not find that Dr. Bell's choice to exclude the short and long units is warranted, and does not find Dr. Bell's testimony and supporting documents persuasive as to why the market should be divided in such a manner.

Thus, based on the ample testimony and other evidence that the devices compete within the same "5 mm advanced energy market,"[23] the Court concludes that Tyco has proved the existence of a single advanced energy market, in which both parties, and both types of technology, compete.

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[23] Ethicon's accused Harmonic WAVE Device is not a 5mm device, and because of this, Dr. Ugone excluded the WAVE from his lost profits/causation to lost sales analysis. The WAVE also does not have a curved blade—indeed, the only remaining valid claim that the WAVE has been found to infringe is claim 3 of the '544 patent, the "dual cam" claim. The Court agrees that the fact that the WAVE does not fit down a 5mm should preclude it from being part of this "but for" world and agrees that the WAVE should not be considered as part of any lost profits analysis.

a) Details of Market Allocation and Reconstruction

Under Dr. Ugone's model, in the "actual market" in 2010, where the infringing products existed, Tyco had a twenty–four percent market share. (*See* Ex. 20 to Ugone Expert Report [PTX 509].) He opined that in 2010, "but for" the accused products, the market would include Ethicon's B and K "immune" ultrasonic products, Ethicon's EnSeal products, Tyco's AutoSonix and LigaSure products, and a small number of other competitors, and Tyco would have a 54.2% market share. (2012 Tr. at 1132.) For 2011, Tyco's "actual" market share was 27.5%, and Dr. Ugone's market reconstruction for 2011 posits that "but for" the infringing devices, Tyco would have had a 60.2% market share. (*Id.* at 1135:17–21.)

Part of Dr. Ugone's reasoning in allocating the market in this way was because there is "documentation that surgeons were unhappy with some of the attributes of the immune products, . . . you can't just say in the year 2000 the immune products had a certain market share and . . . put it down in 2010." (*Id.* at 1133:1–5.) Because the immune products essentially "got replaced by the accused products" (*id.* at 1133:6), Dr. Ugone disagreed with Dr. Bell's analysis that in the "but for" world, the immune products would essentially step in for the accused products' sales. Instead, he concluded that in the "but for" world without the accused products, the immune products would have had between a seven and nine percent market share. (*Id.* at 1134:5–6.) Though in the "actual world" in 2010, the immune products had, by Dr. Bell's calculation at most 0.2% of the market share (*see* Exs. F and F-1 to Bell Expert Report), Dr. Ugone opined that in the "but for" world, the immune products would have had the benefit of more aggressive marketing, and perhaps Ethicon, 'in order to compete with the inferior products," would have lowered the price of the immune products, which led to his conclusion that Defendant's

immune products would have a seven to nine percent market share allocation (2012 Tr. at 1139). The Court agrees that the record does not support Dr. Bell's opinion that the 86.9% market share held by the immune products in 1999 should govern the market share allocation many years later, as it does not give due regard to the significant technological advances made in the market in the interim.[24]

While the Court rejects Dr. Bell's construction, the Court also finds problematic Dr. Ugone's market reconstruction for 2010 and 2011, in which the RF products such as EnSeal and LigaSure are estimated to take a substantially larger part of the advanced energy market. Dr. Ugone relied on a report conducted by the Millennium Research Group ("MRG") ("US Markets for Vessel Sealing Instruments 2010" [DTX 2072]) which projected that over time RF products would gain a larger and larger market share of the advanced energy market. Dr. Ugone reported that the MRG report projected that by 2014 the relative market shares of those two energy sources would be nearly fifty–fifty, which Dr. Ugone described as showing that the market is "split." (2012 Tr. at 1137.) Dr. Ugone therefore opined that there was a reasonable probability that in the "but for" world without the accused products, Tyco's RF products would have a higher share of the advanced energy market.

Though helpful to Tyco's contention that RF technology is on the rise, the MRG document also contains evidence which undercuts Tyco's "but for" market reconstruction. It clearly describes ultrasonic and RF technology as having separate

[24] Dr. Ugone also raises the significant point that pursuant to the 1999 settlement between Tyco and Ethicon, "no substantial, functional, or performance–related changes could be made to the Immune Products." (Ugone Rebuttal Report [PTX 611] ¶ 41). This 1999 Settlement Agreement similarly precludes Tyco from making any such functional/performance–related changes to its own AutoSonix device making it difficult to extrapolate, in a "but for" world, how well either the AutoSonix or the other immune products would have sold relative to each other or competitors' products.

strengths. For example, in describing the "ultrasonic vessel sealing instrument market" writ large, it reports on the rise of laparoscopic surgery and its corresponding effect on ultrasonic device sales:

> Many surgeons are recognizing the advantages of using ultrasonic technology—notably the ability to cut and coagulate tissue simultaneously, a lower risk of charring, . . . and less thermal damage to surrounding tissue. For these reasons, sales of laparoscopic ultrasonic instruments were nearly double that of open units in 2009.

(MRG at 20.) The document also highlights the rise of RF technology, emphasizing its relative strength in open procedures, because of the sealing capabilities of RF technology: "[s]ome physicians, however, prefer RF technology in open settings, which will limit growth somewhat. In these procedures, cutting may be performed by any number of means, so sealing and achieving hemostasis become paramount. (*Id.*; *see also id.* at 27 ("Compared to ultrasonic devices, the improved sealing capability of RF devices makes them particularly effective in open surgery. . . . Sealing is more crucial to the procedure's success, however, and *it is the specialty of RF* devices.") (emphasis added).)

Ethicon also presented evidence that Tyco, while marketing its LigaSure devices, pursued a separate path, "Project Milwaukee," to commercialize and market another ultrasonic device, called the Sonicision. In this "Project Milwaukee" document (Dec. 22, 2008 Project Milwaukee Board of Directors Executive Summary [PTX 513/DTX 2196]), Tyco detailed how it was recommending to its board of directors to purchase and enter into a "development agreement and manufacturing arrangement with Syntheon, LLC" which would provide an "[u]ltrasonic market segment entry point" (*Id.* at 2) and enable it to compete in the "large and lucrative ultrasonic vessel sealing/dissection market segment, currently led by . . . Ethicon" (*id.*). In this document, Tyco describes the vessel sealing market as having "two primary and distinct market segments," and that the

ultrasonic segment accounts for "60% of the overall market," and the RF energy segment accounts for "roughly 40%." (*Id.* at 4.) Thus, Tyco's description of the vessel sealing market in 2008 does not support Dr. Ugone's conclusion that RF devices would dominate the 2010 market in a "but for" world.[25]

As recently as in 2010, in its marketing materials and product launching book for its LigaSure 5–millimeter instrument, Tyco trained its sales representatives to distinguish between the cutting and sealing capabilities of harmonic versus RF technology. (*See* LigaSure 5mm Launch Book [DTX 2076].) In a section entitled "Positioning," the Launch Book specifically identifies Ethicon's Harmonic Scalpel as a competitor, instructing its representatives on "how to combat [Ethicon's Harmonic Scalpel] message," by emphasizing that "Harmonic is a tool for dissection. LigaSure is a tool for vessel sealing." (*Id.* at THG 03125.) Philip Roy dismissed the description that "harmonics cut, RFs seal" as merely identifying "the primary function" of the devices. He testified that "if I look at the strengths of the devices for choosing based on preference, I can look at the Harmonic as a better dissector than LigaSure, I can look at LigaSure as a better vessel sealer, but they both dissect and they both seal vessels." (2012 Tr. at 191:6–15.) Mr. Roy is correct, as shown by the trial record, that both technologies can cut and seal, but this testimony fails to account for surgeon preference, which is exemplified in Tyco's marketing materials and which surely would play a role in a "but for" market reconstruction.

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[25] *See also* January 2009 Covidien Global Market Assessment, LigaSure V+ [DTX 2075] at 04601 ("The LigaSure V has a great chance to take major market share of the Gyrus GYN business because of the grasping capabilities of the LigaSure V+. . . . Unfortunately, we will not see the same degree of conversion from Harmonic to LigaSure V because Harmonic users like the dissection capability of the Harmonic Scalpel. A lot of surgeons who use Harmonic are aware the LigaSure is a better sealer, but *they still use Harmonic for its dissection purpose*. It will be harder to convert some of these users because of the limited dissection capability of the LigaSure V+.") (emphasis added).

"Reconstructing the market, by definition a hypothetical enterprise, requires the patentee to project economic results that did not occur." G*rain Processing Corp. v. Am. Maize-Products Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999). The Federal Circuit has admonished that, "[t]o prevent the hypothetical from lapsing into pure speculation, [it] requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture." *Id.* While Dr. Ugone may be correct that the future of the advanced energy market is likely closer to "split" in terms of the usage of RF and ultrasonic energy devices, the Court is not persuaded by the evidence that it is more likely than not that the "but for" world of 2010 and 2011 would have involved such a drastic shift in purchasing and using RF devices.

A fair and accurate reconstruction of the "but for" world must take into account "alternative actions the infringer foreseeably would have undertaken had he not infringed," including "any alternatives available to the infringer." *Grain Processing Corp. v. Am. Maize Prods.*, 185 F.3d 1341, 1350–51. "The competitor in the "but for" marketplace is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner." *Id.*

Here, it is undisputed that Ethicon had its immune products before the patents–in–suit issued, and continued to market and sell these immune products, though to a significantly lesser degree, once the accused products were placed on the market. While the Court disagrees with Dr. Bell's "but for" world, projecting that the immune products would have a dominant share of the advanced energy market, the Court similarly rejects Dr. Ugone's conclusion that RF technology would have taken over the advanced energy market to the extent he claims, such that Tyco would have a fifty–four percent market share of instrument sales in 2010, and a sixty percent market share in 2011.

"[M]arket reconstruction, though hypothetical, requires "sound economic proof of the nature of the market." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1355 (Fed. Cir. 2001) (citing *Grain Processing*, 185 F.3d at 1350. In *Mor–Flo*, as here, the plaintiff had shown demand for the patented product (there, heaters made with foam insulation), and had established that it had the capacity to "absorb [defendant's] share of the market," which Ethicon does not contest here. However, in *Mor–Flo*, the plaintiff "produced specific evidence that it had lost sales to Mor–Flo's infringing heaters," *Mor–Flo*, 883 F.2d at 1579, including retailers' testimony that they lost sales to *Mor–Flo*. *Id.* Concluding that there was "nothing speculative about these losses," the Federal Circuit noted that "it is eminently reasonably for the district court to infer that State could have sold its market share of More–Flo's infringing sales." *Id.*

Though some evidence was presented showing the substitutability of RF and ultrasonic devices in certain contexts, the record was also substantial that in general, consumers preferred ultrasonic energy for cutting, and RF energy for sealing, and no evidence was presented from which it could be properly inferred that if the most successful ultrasonic devices were taken off the market—i.e., the accused products—surgeons would have simply converted to RF, despite its recognized cutting deficiencies. This falls far short of the "specific" and "far from speculative" evidence of lost sales produced in *Mor–Flo* that led the Federal Circuit to affirm the district court's award of lost profit damages.

Accordingly, the Court concludes that Tyco has not proved it more likely than not that its LigaSure/RF products would have enjoyed this larger market share and therefore, Tyco's prima facie case for lost profit damages fails.

B. Reasonable Royalty

A reasonable royalty is the minimum measure of damages in a patent infringement action. *See King Instruments v. Perego*, 65 F.3 941, 947 n.2 (Fed. Cir. 1992). It is based on what a "hypothetical negotiation" between the patentee and the infringer would yield, and courts typically look to the factors articulated in *Georgia–Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), to determine this rate. *See ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868, 869 (Fed. Cir. 2010) (the *Georgia–Pacific* factors are "[a] comprehensive (but unprioritized and often overlapping) list of relevant factors for a reasonable royalty calculation.").[26]

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[26] The *Georgia–Pacific* factors are:

1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
3. The nature and scope of the license, as exclusive or non–exclusive; or as restricted or non–restricted in terms of territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

The Federal Circuit has "sanctioned the use of the *Georgia–Pacific* factors to frame the reasonable royalty inquiry," *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed.Cir.2011) (reasoning that the *Georgia–Pacific* factors "properly tie the reasonable royalty calculation to the facts of the hypothetical negotiation at issue."). The Court therefore considers all other *Georgia–Pacific* factors in light of factor fifteen—i.e., what a hypothetical negotiation would have yielded between Tyco and Ethicon at the time the infringement began. Both parties' experts agree that such a negotiation would likely have taken place in May 2000, before the issuance of the '050 patent. (See 2012 Tr. at 1475.)

The parties' experts considered the fifteen *Georgia–Pacific* factors, and predictably reached significantly different conclusions: Dr. Ugone argues that Tyco is entitled to a reasonable royalty rate of twelve percent, while Dr. Bell opines that a reasonable royalty rate would 2.6%.

Turning to factors one and two, Drs. Ugone and Bell each considered several licensing agreements between Tyco, Ethicon, and outside parties that they argued would be more or less relevant in determining what would be a reasonable royalty rate agreed to by Tyco and Ethicon: (1) the October 16, 1996 Mixonix/Tyco agreement, with a royalty rate of five percent; (2) the June 7, 2008 SRA/Tyco agreement, with a royalty rate of five percent; (3) the November 3, 1995 Surgical Design/Ethicon agreement, which identified a

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13. The portion of the realizable profit that should be credited to the invention as distinguished from non–patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee- who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention- would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

royalty rate of 1.5%; (4) the December 29, 2004 Intuitive, Inc./Ethicon License, Development and Commercialization Agreement; (5) the June 4, 1998 Olympus/Ethicon agreement with a rate range of three to five percent; and (6) the 1999 Settlement Agreement between Tyco and Ethicon. (Ugone Expert Report ¶¶ 159–73; Bell Expert Report ¶¶ 121–35.)

It is notable that in the 1996 Misonix/Tyco agreement, that Misonix granted Tyco/USSC a license to its '050 patent, one of the patents in suit, and set a 5% royalty rate. Dr. Ugone opined that this agreement is not probative of the reasonable royalty rate because Misonix and Tyco were "cooperators," rather than direct competitors, as Tyco and Ethicon indubitably are (Ugone Expert Report ¶ 160). He reasoned that if they enjoyed a cooperative relationship, there would be less incentive on Misonix's part to drive up the royalty rate. Through the agreement, Misonix and Tyco jointly developed technology, with Misonix responsible for engineering all of the ultrasonic parts of the device, while Tyco was to engineer the jaw mechanism, actuation system, handle, and the outer shells of the hook and ball probes. (Bell Expert Report ¶ 124; Manna testimony, 2007 Tr. at 386–87.) Dr. Bell also considered this agreement, and relied on it to set a five percent rate as the upper end of his royalty range. (*See* Bell Expert Report ¶ 137.)

As to the SRA/Tyco agreement, also with a five percent royalty rate, Dr. Ugone concluded that because the technologies at issue there—the right to develop and commercialize products "with regard to all surgical fields excluding orthopaedic surgery, neurosurgery, dental and maxillofacial surgery and dentistry," and "live animal research or testing in animal laboratories" (*see* Covidien–SRA Agreement at 4, 5, 8, and 11–12)—are not sufficiently related to the patented technologies in suit, the five percent royalty rate was not probative of the terms of a Tyco/Ethicon hypothetical negotiation.

Neither of these two licenses with Tyco involves agreements between "head to head" competitors, such as Tyco and Ethicon. Dr. Ugone also opined that the fact that Tyco has not granted any other licenses with respect to the patented technology that forms the basis of this lawsuit, would drive up the royalty rate.[27] Because of these substantial dissimilarities, the Court does not find that the five percent royalty rate contained in these Tyco license agreements necessarily indicates an upper ceiling of the reasonable royalty rate.

As to license agreements between Ethicon and other entities, the Court finds that the Surgical Design/Ethicon agreement [DTX 1669] with a 1.5% royalty rate is not probative of what Ethicon would pay Tyco for several reasons. The patented technology at issue there was significantly more limited than the patents in suit: it involved Ethicon's receipt of a license to "make, have made, use, sell, or otherwise dispose of" a patented "Ultrasonic handpiece design." The license covered components used for the assembly of a licensed instrument, including a blade and grip housing. Ethicon was limited to a "licensed field," which specifically excluded Ethicon from working in "the fields of ophthalmology, dentistry and otorhinolaryngology." (Surgical Design/Ethicon Agreement ¶ 2.4.) In exchange for licensing these rights, Ethicon agreed to pay Surgical Design a $200,000 lump sum, plus a royalty of 1.5% of net sales. Dr. Ugone emphasized that this agreement was from 1995, which "significantly predates" the date of the hypothetical negotiation, and consequently probably does not account for the success of

[27] Ethicon had tried to procure a license agreement with Tyco as to this particular patented technology, but these negotiations eventually broke down. (*See* Kreger Testimony, 2012 Tr. at 1653:20–21 ("In late 2003, early 2004, the negotiations broke off and there was no license agreement.").)

ultrasonic technology that would have been a factor in 2000. (Ugone Expert Report ¶¶ 168–69.)

The parties also considered a 1998 "Alliance Agreement" between Olympus and Ethicon, which built upon a previous Alliance Contract from 1992. (2012 Tr. at 1477–78; Bell Expert Report ¶ 125.) This particular agreement granted Olympus a nonexclusive license to the Davison '055 patent to "make, have made, use, sell, or have sold products in the same field." (Alliance Agreement [DTX 2146] at ETHI-00025215–216, 234.) There, both parties cross–licensed their patents at a zero percent royalty rate, agreeing that if either party wanted to add a patent to the agreement, the parties would negotiate royalty terms for any patent to be added. The Agreement further provided that the negotiated rate was not to exceed three percent of net sales, with three percent royalty rate to be set as the default if the parties could not agree. (Bell Expert Report ¶ 127 (citing Alliance Agreement at ETHI-00025217).) If a second patent was added that applied to the same product, the rate could be negotiated to up to five percent. (Ugone Testimony, 2012 Tr. at 1164:4–8.) Dr. Bell considered these three or five percent rates to be the "ceilings" provided for in this Agreement. (Bell Testimony, 2012 Tr. at 1478:5–8.)

Dr. Ugone, however, viewed the last clause of the Alliance Agreement as particularly interesting, in that it provided that in the event of a termination of the Agreement, "the royalty rate for any patent licensed by such terminating party . . . shall be doubled for the remaining term of the license." (2012 Tr. at 1164:9–20.) Dr. Ugone explained that he found this provision especially relevant because it revealed what would happen if the relationship between the licensing parties turned competitive:

> So, what this is saying is that if they brought extra patents into this agreement, and you get a three percent on one patent, a three percent on another, so you have more than one patent, and then you apply it to a

> licensed product, it maxes out by—at five under the Alliance Agreement. But if you have multiple incremental patents applied to the same product, and then the alliance is terminated, it goes to ten percent. So, what this says to me is it brings in and has this shift from the alliance agreement to a competitive situation. If the alliance agreement were to be terminated, a licensed product that has multiple incremental patents could go up to ten percent royalty rate.

(2012 Tr. at 1165:2–16.)

Dr. Ugone also considered an agreement between Ethicon and Intuitive Surgical, which Dr. Bell considered, but rejected as not being sufficiently relevant. There, the parties entered into a "license, development and commercialization agreement" to co–develop a Harmonic curved shear reusable instrument to be used with Intuitive's own surgical systems. (December 29, 2004 Ethicon/Intuitive Agreement [DTX 1660] at EES0169396–424.) As part of this agreement, Ethicon granted Intuitive a nonexclusive worldwide license to its Davison '055 patent, with a sixty–six dollar per unit royalty payment. Dr. Ugone opined that while entered into after the date of the hypothetical negotiation, it is highly relevant because it gives an idea of the value that Ethicon placed on the technology in its Davison patent. Dr. Ugone determined that based on the per unit selling prices of the Harmonic Insert sold by Intuitive Surgical (a range of $376 to $624), a per unit royalty payment would be equivalent to eleven to eighteen of the per unit revenue of the Harmonic insert. (Ugone Expert Report ¶ 173.)

Dr. Bell rejects this agreement as non–comparable, describing it as a collaborative agreement, and asserting that Tyco and Ethicon's hypothetical negotiation would not have involved an agreement to "co–develop" technology. While the Court agrees that non–competitive negotiation settings offer little of comparative value, the value that Ethicon assigned to licensing its Davison '055 patent, which Dr. Bell describes as "one of the foundational patents . . . of ultrasonic" (2012 Tr. at 1477:17–18), relevant to the extent

it reflects that Ethicon granted a license at a relatively high royalty rate to its Davison patent (without cross licensing) for a technology that shares some common features with the ultrasonic patents in suit.

Finally, Dr. Bell considered the 1999 Settlement Agreement between Tyco and Ethicon, under which no royalties were payable to either party. However, this settlement agreement was a means of settling previously existing disputes, granting immunity to specific "immune products," and providing that, "[t]he parties also recognize that unasserted claims of patent infringement may exist against each other and wish fully to resolve these existing, unasserted claims." (1999 Settlement Agreement at EES0169383.) As such, its context does not give the Court guidance as to what a licensing negotiation between the parties as to these patents would likely look like.

As to *Georgia–Pacific*'s factors four and five—Tyco's established licensing policy and the commercial relationship between the parties—the Court finds that the nature of the intensely competitive relationship, and the fact that Tyco has not licensed the patents in suit to others would drive up the reasonable royalty rate.[28]

Considering factor eight—"[t]he established profitability of the product made under the patent; its commercial success; and its current popularity"—the patents and ultrasonic surgical instruments derived from the patented technology were enormously successful. Dr. Bell argues that in fact, given that both parties would recognize the market potential for ultrasonic surgical devices, this factor, though important, would not have a significant impact on the royalty rate in either direction. (Bell Expert Report ¶ 150.) Dr. Ugone opined that this factor would drive up the rate, and testified that the commercial

[28] Neither Dr. Ugone or Dr. Bell considered factors six or seven—the role of the patented product on the sales of other items, and the duration of the patent—to be probative of setting a reasonable royalty rate.

success of the products would be a "top of the mind" consideration for both parties, because

> Tyco would be saying if I license a competitor, I may lose some sales and I'm going to lose incremental profitability. Ethicon is going to be saying I need these patents in order to sell my products lawfully, there is a high profitability associated with that, if I don't get a license agreement, my profits are at risk.

(2012 Tr. at 1170:5–12.) The record shows that Ethicon benefited significantly from introducing its accused products to the marketplace—indeed, the introduction of the accused products altered the market and Ethicon's sales of immune ultrasonic surgical devices simultaneously dropped substantially. (2012 Tr. at 1171:1–14; PTX 693 at 77.) The Court is persuaded that this factor would push the rate higher.

The experts disagree over the relevance of factors nine and ten—the advantages of the patented technology over older modes or devices and the nature of the invention and benefits to the user. Were it not for the Court's finding of invalidity as to significant aspects of the patented devices, such as rotation and ability to fit down a 5mm trocar, this factor may well have driven the rate up significantly. However, the Court will only consider the role of the curved blade technology and the added power of the dual cam design which are features that may have played a role in demand for the accused products, but would not be the sole considerations between the parties at the hypothetical negotiation stage. Indeed, Dr. Ugone himself testified, "[t]he fact that there [are] market trends towards minimally invasively surgeries, toward laparoscopic surgeries, and all of what these patents do is meet that market demand for those types of surgeries. So, that all goes into nine and ten here." (2012 Tr. at 1171:24–1172-6.) He concluded that these factors "would lead to and maintain upward pressure on the negotiated royalty rate during the hypothetical negotiation." The record shows that at the time that of the

hypothetical negotiation, Ethicon had the benefit of the Davison '055 patent and the immune products, which also play a role in the market trends toward minimally invasive surgeries that Dr. Ugone described, and consequently the Court does not find that these two factors would exert particular upward pressure on the rate negotiation.

However, since the release of its LCS devices on the market, Ethicon has continued to market and benefit from its curved shears devices, thereby availing itself of aspects of Plaintiff's patented technology. Thus, the Court finds that factor eleven—the value of the patented technology to Ethicon—would have a role in raising the negotiated royalty rate.

Ultimately, Dr. Ugone opined that a reasonable royalty rate would fall between twelve and fifteen percent, while Dr. Bell defined his royalty rate range as between 1.5% and five percent, recommending a 2.6% rate. After a consideration of the *Georgia–Pacific* factors and Dr. Ugone's and Dr. Bell's expert reports and trial testimony, the Court finds that neither expert's proposed royalty rates sufficiently account for the parties' respective positions, strengths, and weaknesses.

The Court concludes that a rate of eight percent is appropriate. This rate is sufficiently higher than the five percent rate that Misonix required when it licensed the '050 patent to Tyco, which reflected their status as cooperators rather than competitors. Further, the eight percent rate takes into account the fact that Ethicon had its own ultrasonic technology, in the form of the dated Davison '055 patent and the immune products, yet also accounts for the fact that Ethicon's accused products, which contain patented features, were far more successful than its immune products.

The Court also concludes that this lower royalty rate adequately accounts for the fact that a proposed royalty rate of twelve percent as to the WAVE's sales would have been entirely improper, given that the WAVE does not use a curved blade.

C. Conclusions on Damages

As the Court has concluded lost profits damages are not appropriate, applying a royalty rate of eight percent to $1,751,000,000 of infringing sales from April 1, 2004 to March 31, 2012 yields royalty damages of $140,080,000.

D. Other Relief Sought

1. Willful Infringement

Tyco also asserts that the record supports a finding of Defendant's willful infringement. A patentee must prove willful infringement by clear and convincing evidence. *See In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). The Federal Circuit requires a threshold showing of "objective recklessness," that is, that Tyco must show that it is highly probable that Ethicon "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* If this "objective standard" is met, then Tyco must also demonstrate that this "objectively–defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Id.*

As to the objective prong, the evidence showed that Ethicon had acquired UltraCision in 1995 and since at least 1995, Ethicon had been working on developing a 5–mm ultrasonic surgical instrument that would cut and coagulate tissue. Ethicon has asserted its non–infringement and invalidity defenses under § 102(g) and § 103 since

2002, when the '286 patent was issued. Verne Kreger, in–house counsel for Johnson & Johnson testified that he became aware of the '286 patent shortly after it issued, and that he recommended to Johnson & Johnson's head of Research and Development that they should obtain the opinion of outside counsel as to whether the '286 patent was invalid, or whether the LCSC–5 infringed. (*See* 2012 Tr. at 1685.)

Mr. Kreger testified that he "was quickly able to dismiss all of the claims that were directed to the cam. . . . And really what I was focusing on was claim 1 of the '050 and claim 1 of the '286." (*Id.* at 1689:8–15.) He further recalled, "we had a position of obviousness based on a combination of Davison and the references that I talked about . . . with respect to the claim 1 of the '050 patent and claim 1 of the '286 patent." (2012 Tr. at 1693:4–7.) He testified that armed with his own "preliminary" opinions about the invalidity and non–infringement of Ethicon's devices and the '050 and '286 patents, Ethicon initiated licensing negotiations with U.S. Surgical. Ethicon then waited until the negotiations terminated in January 2004, at which time Kreger "began to formalize and collate all of the references" for his obviousness opinion. (*Id.* at 1709:1–7.) Mr. Kreger conceded that the invalidity opinions he solicited from outside counsel did not include a § 102(g) defense based on the prototypes, but that he had "advised the business . . . that we had the potential of a 102(g) defense based on the prototype, . . . and a hunch I had with respect to U.S. Surgical's earliest priority date." (*Id.* at 1709:18–22.)

Outside counsel submitted opinions on infringement and invalidity, the results of which were compiled by Mr. Kreger into a summary document dated June 9, 2004. (*See*

PTX 84.) In this summary, there is a reference to the May 17, 1996 UltraCision prototype drawing (PTX 84/DTX 1632 at 1), and a note that "EES [Ethicon EndoSurgery] also has an argument of invalidity with respect to at least those claims marked with a "Y" . . . on the basis that EES was the first to invent the claimed subject matter. EES has a prima facie argument based on the date of May 17, 1996 of the Ultracision drawing, which predates USS's [U.S. Surgical's] earliest filing date of Oct. 4, 1998." (*Id.*)

Mr. Kreger's summary indicates that as to the '286 Patent, Ethicon had obtained § 103 invalidity opinions (with the Davison '055 patent and Robinson '142 patent as prior art references) as to nearly all claims, and outside opinions on non–infringement as to claims 4, 8–14, 17–18, and 20. (*See* PTX 84 at JB10020–21.) As to the '544 patent, outside counsel provided § 103 opinions (with Davison '055, Robinson '142, and European Patent '662 as prior art references) as to all claims, and non–infringement opinions as to all claims. (*Id.* at JB10022–26.) As to the '050 patent, there were § 103 opinions (with Davison '055, Robinson '142, European Patent '315, the '501 patent, European Patent '662, and "UDwg" as prior art references) as to all claims but claim 2 (*see id.* at JB10034), and non–infringement as to all claims except 5–6 and 8–10 (*id.*). (*See also* Opinions of Outside Counsel [DTX 2440, 1609, 1611, 1613, 1615–1616].)

Under Seagate's objective standard, "both legitimate defenses to infringement claims and credible invalidity arguments demonstrate the lack of an objectively high likelihood that a party took actions constituting infringement of a valid patent." B*lack & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 F. App'x 284, 291 (Fed. Cir. 2008).

The record shows that Ethicon's engineers and in–house counsel, as well as outside counsel, have long maintained their non–infringement position, particularly with respect to camming claims. As indicated in the section on infringement, the question of infringement as to the camming claims is a close factual question. While the Court has concluded that plaintiff has proven that it is more likely than not that the accused devices infringe the camming claims, based on the record at trial, Tyco has not proven by clear and convincing evidence that Ethicon acted despite an objectively high likelihood that its products infringed the camming claims of the patents in suit. Further, as discussed *supra*, Ethicon's invalidity defenses are more than "credible." *Black & Decker*, 260 F. App'x at 291.

Here, the evidence gives no indication that Defendant simply took an arbitrary and unprincipled position of noninfringement and shopped for supporting outside legal counsel opinions. It is clear that Tyco and Ethicon were both conducting their respective research and development within the same general timeline. Ethicon purchased UltraCision in 1995 with the specific intention of creating an ultrasonic surgical device that worked as well as the Davison LSC–10 device, but that could fit down a 5–mm trocar, and continued working on its prototype devices through 1998. (*See supra* Part III.A.) Indeed, with the purchase of UltraCision in 1995, Ethicon may have bought itself a credible § 102(g) defense, because the subsequent years of Defendant's testing and developing the prototypes were in such close temporal proximity to the filing of Tyco's patents, that Tyco cannot meet its burden of proving by clear and convincing evidence

Seagate's objective prong because the years of continued animal labs and development work to improve the UltraCision and Ethicon prototypes and to create the LCS–K5 and B5 devices demonstrate a legitimate defense and thus lack of willfulness.

As to the obviousness defense, though the Court rejects Ethicon's § 103 position (*see supra* Part III.C.2), it, too, is a credible defense based on the argument that the Davison '055 patent, which is essential prior art to both parties' ultrasonic patents, rendered the asserted claims obvious. That Ethicon did not prove its obviousness by the heightened standard of clear and convincing evidence does not render Defendant's defense outlandish or frivolous. Indeed, that the Davison '055 patent presented a credible challenge to the asserted patents' validity leads to the conclusion that Plaintiff also fails to meet its own heightened burden of proof by clear and convincing evidence on willful infringement. Thus, the Court finds that Tyco's willful infringement case does not make it past *Seagate's* objective prong.

2. Permanent Injunction

Tyco has also requested that the Court grant a permanent injunction in its favor. However, the Court does not find that Tyco has met its burden of proving that injunctive relief is warranted.

A plaintiff seeking a permanent injunction must satisfy a four–factor test to qualify for such relief. A plaintiff must demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). "These familiar principles apply with equal force to disputes arising under the Patent Act." *Id.*

Most importantly, the Court finds that Plaintiff did not prove the first prong, as Philip Roy, the first witness who testified at trial, and who spoke on the subject of Tyco's ultrasonic devices in relation to Ethicon's, spoke of "irreparable harm" suffered by Tyco in terms of the damage to its reputation, but was unable to articulate why if Tyco has endured infringement and harm to its reputation since 2004, it never sought preliminary injunctive relief. (2012 Tr. at 209–210.) Throughout trial, Tyco has been emphatic as to its entitlement to lost profits and to a certain royalty rate, which further supports the position that "remedies available at law, such a monetary damages," are fully adequate to compensate for Tyco's injury.

The Court finds that the public interest prong cuts both ways, as there is certainly an interest in "protecting the rights of patent owners," *see Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 985 (W.D. Tenn. 2006), as well as an important consideration that a permanent injunction would pull many devices that are presently used in surgery off the market. *See, e.g.*, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, CV-03-0597-PHX-MHM, 2009 WL 920300, at *9 (D. Ariz. Mar. 31, 2009) *aff'd*, 670 F.3d 1171, *opinion vacated in part on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012) *vacated in part on reh'g en banc*, 476 F. App'x 747 (Fed. Cir. 2012) ("Given the utility of Gore's infringing products, both Counterpart and Non–Counterpart, the important role that these products play in aiding vascular surgeons who perform life saving medical treatments, sound public policy does not favor removing Gore's items from the market. The risk is too great. Placing Gore's infringing products out of reach of the surgeons who rely on them would only work to deny many sick patients a full range

of clinically effective and potentially life saving treatments. The Court finds that the strength of this factor alone precludes it from imposing a permanent injunction.").

The Court has also considered the "balance of hardships" and concludes that a "remedy in equity" is not warranted. These parties, self–described as the Coke and Pepsi of the surgical tool market, are both giants in the industry, and the balance of hardships does not tip sufficiently in Plaintiff's favor to warrant such an extreme remedy.

3. Prejudgment Interest

Tyco seeks prejudgment interest. "An award of prejudgment interest serves to make the patentee whole because the patentee also lost the use of its money due to infringement." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1361 (Fed. Cir. 2001) (citing *General Motors*, 461 U.S. at 655–56). "In *General Motors*, the Supreme Court made prejudgment interest the rule, not the exception." *Id.* As "prejudgment interest should be awarded absent some justification for withholding such an award," *see General Motors*, 461 U.S. at 655–57, and neither party has argued in favor of such a withholding, the Court awards prejudgment interest to Tyco. Neither party has advocated for a particular interest rate, and therefore the Court awards prejudgment interest at today's prime interest rate of 3.25%, which yields $36,420,800 in total interest earnings for a total award of $176,500,800.00 in damages. *See Applera Corp. v. MJ Research Inc.*, No.98CV1201(JBA), 2005 WL 2084319, at *2 (D. Conn. Aug. 29, 2005) (awarding prejudment interest to patentee using the prime rate of interest).

VI. Conclusion

For the reasons set forth in this Memorandum of Decision, the Court awards $176,500,800.00 in damages to Tyco. Tyco's oral motions for judgment as a matter of law [Doc. ## 197, 201] are DENIED, and Ethicon's oral motions for judgment as a matter of law [Doc. ## 196, 202] are also DENIED, as is its motion to strike the testimony of Dr. Durfee [Doc. ## 203, 212].

The Clerk is directed to enter judgment in favor of Tyco in the amount of $176,500,800.00 and to close the case.

IT IS SO ORDERED.

/s/
Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut this 28th day of March, 2013.