IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORPORATION Plaintiffs, v. ETHICON ENDO-SURGERY, INC. Defendant.	)	Civil Action No: 3:10cv0060 (JBA)

PLAINTIFFS' OPPOSITION TO ETHICON'S POST-TRIAL BRIEF FOR JUDGMENT PURSUANT TO RULE 52

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Plaintiffs Tyco Healthcare Group LP and United States Surgical Corporation (collectively "Tyco") respectfully submit this memorandum of law in opposition to defendant Ethicon Endo-Surgery, Inc.'s ("Ethicon") motions for judgment on infringement, validity under 35 U.S.C. §§ 102(g) and 103, willfulness, the availability of lost profits, the calculation of reasonable royalties, and a permanent injunction.

I. PRELIMINARY STATEMENT

Despite the Court's admonition that post trial briefing be limited to submissions that are "not repetitive" of what is contained in the parties' pretrial submissions, Ethicon's Motion for Judgment Pursuant to Rule 52(c) of the Federal Rules of Civil Procedure is largely based on arguments and facts that have already been provided to this Court in the parties' pretrial submissions. With all evidence of record entered and any legal issues fully briefed by the parties, it is apparent now more than ever that Ethicon is anxiously grasping at straws.

As set forth in detail below, Tyco has satisfied, and in some instances exceeded, its respective burdens to prove (1) infringement as to the claims requiring a camming mechanism; (2) demand for the patented features and corresponding entitlement to lost profits; (3) entitlement to a reasonable royalty of twelve percent; (4) willful infringement by Ethicon; and (5) the necessity of a permanent injunction.

Ethicon, on the other hand, has failed to meet its heavy burden of clear and convincing evidence on its invalidity defenses under 35 U.S.C. §§ 102(g) and 103. Concerning invalidity pursuant to 102(g), Ethicon has attempted to couch its failures as the product of allegedly unreasonable high internal standards. Ethicon's own documents and witness statements made in the relevant time period, however, reveal that Ethicon simply was unable to reduce the invention to practice prior to the filing date of Tyco's patents. Ethicon cannot demonstrate under the clear

and convincing evidence standard that the UltraCision and Ethicon prototypes reliably met their intended purpose to cut *and coagulate* tissue.

With respect to its obviousness defense, Ethicon's motion wrongly attempts to shift the burden and improperly argues that Tyco has failed to properly prove nonobviousness. The record evidence demonstrates, however, that Ethicon fell far short of its burden to prove by clear and convincing evidence that the asserted patents are obvious. Ethicon's proffered expert testimony of Dr. Cimino – cursory, driven solely by hindsight, and belied by the factual record – does not support a finding of invalidity.

Accordingly, because Tyco has met its respective burdens and Ethicon has not, Tyco respectfully requests that this Court deny Ethicon's motion for judgment on infringement, validity under 35 U.S.C. §§ 102(g) and 103, willfulness, the availability of lost profits, the calculation of reasonable royalties, and a permanent injunction.

II. STANDARD OF REVIEW

When ruling on a motion under Rule 52(c) of the Federal Rules of Civil Procedure, "the court acts as both judge and jury," *In re Regency Holdings (Cayman), Inc.*, 216 B.R. 371, 374 (Bankr. S.D.N.Y. 1998); *Grant v. Bullock County Bd. of Educ.*, 895 F. Supp. 1506, 1509 (M.D. Ala. 1995). The "court is within its prerogative 'to weigh the evidence, resolve any conflicts in it, and decide for itself where the preponderance lies.'" *Von Zuckerstein v. Argonne Nat'l Lab.*, 984 F.2d 1467, 1475 (7th Cir. 1993), *cert. denied*, 510 U.S. 959, 114 S.Ct. 419 (1993) (quoting *Sanders v. Gen. Servs. Admin.*, 707 F.2d 969, 971 (7th Cir. 1983)); *Fabricated Wall Sys., Inc. v. Herman Miller, Inc.*, No. 08-01313, 2011 WL 5374130, at *1 (D. Conn. Nov. 8, 2011).

III. ETHICON'S MOTIONS FOR JUDGMENT SHOULD BE DENIED

A. Tyco Proved By A Preponderance Of The Evidence That The Accused Devices Have A Camming Mechanism

Ethicon's motion only challenges infringement as to the claims requiring a camming mechanism.[1] With respect to these claims,[2] as set forth in detail in Plaintiffs' Motion for Judgment as a Matter of Law on Infringement of the Asserted Patents (ECF No. 211) (hereinafter "Tyco's JMOL Infringement"), the camming elements are met by the accused devices. Each of the accused products use openings or grooves (cam slots) that impart motion and guide follower parts (cam members), whereby the follower and an actuation member can pivot a clamp. Importantly, Ethicon does not dispute that the accused devices have slots and have cam members (which Ethicon refers to as pins), where the cam members engage in sliding contact with the slots. Moreover, the evidence clearly demonstrated that the slots in the accused products impart motion and guide the movement of the camming members.[3]

Ethicon's argument that the accused devices do not infringe despite having these elements is built on two faulty premises. First, Ethicon improperly argues that because the accused devices do not match the pictured preferred embodiment in the patent, the accused devices therefore do not have a cam mechanism. However, claims are not limited to the preferred embodiment or those found in the figures of the patent. *Eolas Techs. Inc. v. Microsoft Corp*., 399 F.3d 1325, 1336 (Fed. Cir. 2005) ("[A]bsent a clear disclaimer in the specification, the embodiments in the specification do not limit broader claim language."). Under this Court's construction, the camming mechanism of the claims need only have slots that impart motion to and guide the motion of the camming members. *See Tyco Healthcare Group LP v. Ethicon*

[1] For the remaining asserted claims, the Court has already found infringement, Ethicon has stipulated to infringement, and/or Ethicon does not contest through its motion that Tyco's burden of proof has been met.
[2] Claims 11-12 of the '050 patent, claim 8 (and claim 9-14 dependent on claim 8) of the '286 patent, and claims 1-3 (and claims 6, 8-13, 16, 18, and 23-25 dependent on claim 1) of the '544 patent.
[3] *See* Tyco's JMOL Infringement at 4-10, ECF No. 211.

Endo-Surgery, Inc., 411 F. Supp. 2d 93, 100 (D. Conn. 2006) ("*Tyco I*"). Ethicon now wrongly seeks to import additional limitations that require the camming members to contact all portions of the slot. (*See* Ethicon's Post-Trial Brief for Judgment Pursuant to Rule 52 at 4, ECF. No. 209 (hereinafter "Ethicon Br.").) But nothing in the patents-in-suit or the Court's construction supports this requirement. Ethicon's position is even contradicted by its own expert, Dr. Cimino, who testified that the amount of sliding contact is determined by the cam design, and can vary between cam designs. (Trial Tr. vol. 5, 1031-32, July 13, 2012.)

Ethicon's other argument, equally misplaced, is that camming mechanisms cannot share commonalities with other mechanical mechanisms. Nothing in the patents or in the Court's construction mandate that every feature of a camming mechanism be unique and exclusive to cams. That other mechanisms may have sliding contact is irrelevant. Dr. Durfee's testimony that a rack and pinion can consist of a multitude of cams around a circle and a multitude of slots in a line does not negate that when broken down, the single component is a camming mechanism. (Trial Tr. vol. 9, 1775-79, July 26, 2012.) Ethicon's contention that the accused devices cannot have a camming mechanism because it has been identified by other monikers is inapposite. (*See* Ethicon Br. at 8-9.) Ethicon's documents, and even Ethicon's expert, do not identify the features of the accused device in a consistent way. (*See* Ethicon Br. at 9.) Yet this variation has no relevant bearing on the actual issue – which is how the mechanism of the accused devices functions. What the evidence indicates is that the accused devices have the element of and function as a camming mechanism with cam slots that impart motion to and guide the motion of the camming members. (*See e.g.*, Trial Tr. vol. 4, 694 and 702-04, Dec. 6, 2007 (Dr. Durfee testified: "the slots are also guiding that motion around the circle, because the location of the camming members along the circle and how fast they go along the circle is

determined by the position of the cam slot and the shape of the cam slot.").)[4]

The accused products even pass Dr. Cimino's so called "test" for cam mechanisms, namely, if a change in the shape of the cam slot results in a change of the cam profile (*i.e.*, because the guiding function of the cam slot has been altered), it is a cam mechanism. (PTX 481 ¶ 41.) As Dr. Durfee testified, a change in the shape of the cam profile in the accused devices (*i.e.*, the edges of the slots in the ACE, LCS, and CS devices or the edge of the clamp legs in the Wave device) will affect the equation of how motion is transferred from the cam to the follower (*i.e.*, the input/output relationship between the cam and follower). (Trial Tr. vol. 2, 301, 419-20, July 10, 2012; Trial Tr. vol. 9, 1777-78, July 26, 2012.) In sum, Tyco has proven, by a preponderance of the evidence, that the accused devices meet the recited camming elements.

B. Ethicon Failed To Prove Invalidity Under 35 U.S.C. § 102(g) By Clear And Convincing Evidence

As set forth more fully and in detail in Plaintiffs' Motion for Judgment as a Matter of Law of No Invalidity Under 35 U.S.C. 102(g) (ECF No. 210) (hereinafter "Tyco's JMOL No Invalidity"), the burden to prove invalidity under a prior invention theory is a heavy one – clear and convincing evidence – and Ethicon has failed to meet it. *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006).

Despite Ethicon's attempt to now couch its failures as the product of allegedly unreasonable high internal standards, Ethicon's own documents and witness statements show that Ethicon was unable to reduce the invention to practice prior to the filing date of Tyco's patents. Ethicon cannot demonstrate under the clear and convincing evidence standard that the UltraCision and Ethicon prototypes reliably met their intended purpose to cut *and coagulate* tissue. The evidence demonstrates that Ethicon's testing could not show "utility beyond a

[4] *See* Tyco's JMOL Infringement at 7, ECF No. 211.

probability of failure." *Tyco Healthcare Group LP v. Ethicon-Endo-Surgery, Inc.*, 514 F. Supp. 2d 351, 359 (D. Conn. 2007) ("*Tyco II*") (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). Ethicon's devices were not "considered successful for [its] intended purpose" because the evidence clearly indicated that there were "significant unresolved problems [ ] perceived to exist in producing a working embodiment of the invention" which "remained present after the date of alleged reduction to practice." *Wiesner v. Weigert*, 666 F.2d 582, 588 (C.C.P.A. 1981). Hemostasis and effective vessel seals in animal models (*i.e.*, achieving coagulation) remained a significant problem throughout 1997, even after the filing date of the patents-in-suit.

Ethicon's own witnesses and documents evidence significant problems at the time the prototypes were being tested in the pig model.[5] As Ethicon's Rich Goheen summarized it: "[W]e didn't have a reliable device." (Goheen Dep. 53:4-5, Nov. 22, 2005; *see also id.* at 52:21-25.)[6] Ethicon's attempt to point to isolated incidents as "successes," while ignoring the evidence of subsequent failures, does not meet its burden under the clear and convincing standard.

Further, a significant factor in Ethicon's proof is "whether the LCS-5 was reduced to practice as seen by its performance ***under test conditions which approximated "the intended functional setting,"*** *Koval v. Bodenschatz*, 463 F.2d 442, 447 (C.C.P.A. 1972) ***i.e., surgery on humans***." (Ruling on Mot. for Partial Summ. J. at 16, *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 10-00060 (D. Conn. Sep. 23, 2011), ECF No. 91 (emphasis added).) Ethicon's documents and witnesses uniformly pointed to the goat model as the optimal model in which to test the intended purpose of human surgeries.[7] The evidence at trial demonstrated that the prototypes exhibited persistent problems in the goat labs, indicating these devices did not

[5] *See* Tyco's JMOL No Invalidity at 4-8, ECF No. 210.
[6] Designated as read-in testimony for the record, July 27, 2012.
[7] *See* Tyco's JMOL No Invalidity at 9-10, ECF. No. 210.

work for their intended purpose.[8] The evidence further showed that the failures in the goat labs were not limited to large vessels but occurred on uterine arteries of 2 mm or less and on broad ligaments that are approximately 1 mm.[9]

Ethicon's arguments to side-step the significant and persistent failures of the prototypes are unavailing. Ethicon's reliance on Dr. Gallagher's testimony that the devices worked for small vessels is flatly contradicted by the statements of Dr. Gallagher and her Ethicon colleagues made in the relevant time period that characterized the devices as "unacceptable," evinced by 11 of 14 labs (78%) with incidence of hemorrhage between April 17, 1997 and July 14, 1997, noting "[s]ignificant issues related to poor hemostasis" and stating that the device "did not perform acceptably."[10] Moreover, as the evidence clearly showed, Ethicon did not even begin recording vessel size until September 1997. (Trial Tr. vol. 4, 632, July 12, 2012; DTX 1539 at EES0039310.)

Ethicon's argument that the failures were somehow due to changes it was making to the device only emphasize Ethicon's failure of proof under 35 U.S.C. § 102(g). Ethicon's trial and error approach to modifying the prototypes as Ethicon attempted to understand why these devices were not working indicates that Ethicon had not fixed on a conception of the device. Conception is not merely "an idea," but one that is "a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs Wellcome Co. v. Barr Labs., Inc*., 40 F.3d 1223, 1229 (Fed. Cir. 1994); *see also id*. (citing *Alpert v. Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962) for the premise of no conception "where the idea is in constant flux").[11]

Furthermore, Ethicon cannot rely on the Smith/Whipple design of the UltraCision and

[8] *See* Tyco's JMOL No Invalidity at 8-16, ECF. No. 210.
[9] *See* Tyco's JMOL No Invalidity at 12-16, ECF. No 210.
[10] *See* Tyco's JMOL No Invalidity at 10-12, ECF. No 210.
[11] *See* Tyco's JMOL No Invalidity at 16-21, ECF No. 210.

Ethicon prototypes as an earlier conception for the dual cam device that was later reduced to practice and commercialized in 1998. Accordingly, its "Path Two" theory fails. The evidence shows that in July 1997, Ethicon set aside the Smith/Whipple design and searched for new ideas when it became apparent that the prototypes had a critical design flaw. In the course of approaching the redesign, the Ethicon engineers considered a range of ideas before settling on a definite and permanent concept.[12] The redesign also necessitated changes to a number of features of the device.[13] As Ethicon engineer Mr. Bishop explained, "when you make a change to one part, all the parts fit together like a puzzle, so it has a ripple effect throughout the design." (Trial Tr. vol. 4, 592, Dec. 6, 2007.) The redesign effort thus constituted a new and separate conception, separate and apart from the Smith/Whipple design.[14] Importantly, Ethicon did not reach this new conception until *after* the effective filing date of Tyco's patents.[15] Accordingly, the design that Ethicon eventually reduced to practice and incorporated into its commercial devices is based on a conception that occurred after the filing date of the patents-in-suit.

Ethicon's reliance on the discarded Smith/Whipple design and attempts to make this design work cannot also constitute diligence for the later-reduced to practice dual cam design. Unlike *Eolas Technologies, Inc. v. Microsoft Corp.*, where the inventor had demonstrated reduction to practice of the first version of software and then later demonstrated a second improved version (*see* 399 F.3d at 1333), the evidence shows that Ethicon never reduced to practice its original Smith/Whipple design and discarded this first design for a new dual cam concept conceived after the filing of the patents-in-suit. Accordingly, Ethicon has failed to meet its burden to demonstrate invalidity under 35 U.S.C. § 102(g) by clear and convincing evidence.

[12] *See* Tyco's JMOL No Invalidity at 19-21, ECF No. 210.
[13] *See* Tyco's JMOL No Invalidity at 19-21, ECF No. 210.
[14] *See* Tyco's JMOL No Invalidity at 19-25, ECF No. 210.
[15] *See* Tyco's JMOL No Invalidity at 21, ECF No. 210.

C. Ethicon Failed To Prove Obviousness Of The Asserted Claims By Clear And Convincing Evidence

Ethicon's motion regarding obviousness conveniently ignores an essential feature of its case – namely that it is ***Ethicon's burden*** to prove obviousness by clear and convincing evidence, not Tyco's burden to disprove it. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238, 2245-46 (2011). Ethicon's motion wrongly attempts to shift the burden and improperly argues that Tyco has failed to properly prove nonobviousness. Furthermore, contrary to Ethicon's argument that Dr. Durfee did not consider the inventions as a whole, that is exactly what Dr. Durfee's rebuttal addressed: why the isolated features identified by Dr. Cimino from non-analogous prior art would not work if one attempted to integrate them into an ultrasonic device as claimed by the patents-in-suit.

The record demonstrates that Ethicon fell far short of its clear and convincing evidentiary burden. Ethicon's proffered expert testimony of Dr. Cimino – cursory, driven solely by hindsight, and belied by the factual record – does not support a finding of invalidity. And the record is replete with evidence from Dr. Durfee's rebuttal and others of skill in the art, that demonstrates the claimed inventions were far from obvious.

1. Ethicon Failed To Show An Apparent Reason To Combine Davison with Non-Analogous Non-Ultrasonic Prior Art

Notably, Ethicon cannot point to any testimony or documents that evidence an apparent reason to combine the Davison patent with the non-analogous non-ultrasonic art of the Robinson '142 patent (PTX 311), the EP '315 patent (PTX 316), the EP '662 application (PTX 315), and the Tovey '342 patent (PTX 312) describing mechanical staplers, graspers, cutters, and dissectors, and electrosurgical devices. (*See* Trial Tr. vol. 9, 1793-1815, July 26, 2012.)

"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., Inc.*

v. Apotex, Inc., 655 F.3d 1352, 1360 (Fed. Cir. 2011); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Ethicon must show there was "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does in an obviousness determination." *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350,1356-57 (Fed. Cir. 2007) (quotation omitted); *see also Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1300-01 (Fed. Cir. 2009) ("[I]t remains appropriate for a post- KSR court considering obviousness to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.") (citation and quotation omitted).) Yet, its technical expert, Dr. Cimino, simply opined on separate elements provided in each of the prior art references. (*See e.g.*, Trial Tr. vol. 5, 944-51, July 13, 2012.)

Dr. Cimino conceded that besides the Davison patent, none of the laparoscopic instruments presented in the prior art on which he relied had any disclosures at all concerning ultrasonic technology. (Trial Tr. vol. 5, 992-93, July 13, 2012.) Moreover, nowhere does Ethicon point to testimony from Dr. Cimino or other witnesses that would provide an apparent reason to combine Davison with this prior art. Instead, the evidence of record shows that there are many reasons *not* to combine non-analogous, non-ultrasonic devices. Ethicon's witness Gary Whipple, a former UltraCision employee confirmed that "existing laparoscopic instruments [*i.e.*, non-ultrasonic instruments] were not a whole lot of help as far as [] trying to invent the 5-millimeter ultrasonic clamp device." (Trial Tr. vol. 8, 1379-80, Dec. 12, 2007.) Furthermore, during the prosecution of the very Davison patent it now asserts, Ethicon took *the exact opposite position* it now professes. Ethicon represented to the United States Patent and Trademark Office that non-ultrasonic references were **not analogous** and could not be used to render an ultrasonic invention obvious. (PTX 480 at 26-28.) Ethicon's argument to the contrary is belied by the very

words of this submission which emphasizes that the "reference is a mechanical device which does not employ ultrasonic energy and relies instead on purely mechanical elements for grasping and cutting, the device . . . cannot . . . be said to logically have commended itself to . . . Applicant's problem." (*Id.* at 26-27.)

A reference is not considered within the inventor's field of endeavor merely because it relates to the same industry. *See In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). Yet Ethicon has not pointed to any evidence that shows one of ordinary skill in the art would have looked at other laparoscopic instruments simply because they are all used in surgery. Despite strong evidence that the Robinson '142 patent, the EP '315 patent, the EP '662 application and the Tovey '342 patent were all non-analogous non-ultrasonic art, these are the only references that Ethicon could offer in combination with Davison. Ethicon's obviousness case thus rested on "improper hindsight in the selection of the prior art relevant to obviousness." *See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998).

2. Ethicon Has Failed To Demonstrate That The Skilled Artisan Would Have Had A Reasonable Expectation Of Success With The Combination Of Davison And Non-Ultrasonic Prior Art

Ethicon's obviousness case fails on another essential point. In addition to an apparent reason to combine the references, Ethicon must demonstrate by clear and convincing evidence "that the skilled artisan would have had a reasonable expectation of success in doing so." *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (internal quotations omitted). Ethicon's motion does not even address this requirement.

The disclosures of the Robinson '142 patent, the EP '315 patent, the EP '662 application, and the Tovey '342 patent are devoid of guidance as to how to implement the patented features in a working ultrasonic shears device. (Trial Tr. vol. 5, 991-93, July 13, 2012.) For example, these disclosures do not account for the fact that ultrasonic devices require a very rapidly

vibrating shaft running down the middle of the device which restricts the amount of space available, or the fact that the rapid vibrations transmitted down the entire length of instrument must be isolated from other parts of the instrument. (*Id.*; *see also* Trial Tr. vol. 9, 1810, July 26, 2012.) As Ethicon engineer Gregory Bishop acknowledged, the Harmonic Scalpel devices, *i.e.*, ultrasonic devices, are "real challenges because of the combination of the mechanics and the harmonics." (Trial Tr. vol. 4, 593, Dec. 6, 2007; *see also* Trial Tr. vol. 9, 1793-94, July 26, 2012 (Dr. Durfee testified: "[T]he 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.").)

Ethicon's cursory testimony elicited from Dr. Cimino does not suffice to fill the void left by these prior art references. As Ethicon's motion makes clear, Dr. Cimino simply identified individual claim elements that appeared in one or more non-ultrasonic prior art references. (Trial. Tr. vol. 5, 944-51, July 13, 2012.) He made no attempt to explain how these elements could be combined with the Davison ultrasonic device, let alone why such a combination would instill the artisan with a reasonable expectation of success. (*Id.*) Furthermore, the evidence of record indicates that the skilled artisan would not have had a reasonable expectation of success, but instead would have encountered insurmountable technical challenges.

3. The Combination Of Davison And Other Non-Ultrasonic References Does Not Render The Asserted Claims Obvious

The Davison patent is the only prior art patent cited by Ethicon that is directed to an ultrasonic surgical instrument. The Patent Office considered Davison and allowed the claims of the asserted patents over this reference. (PTX 50 at 2; PTX 52 at 2; PTX 53 at 2.) Ethicon's expert, Dr. Cimino, admitted that Davison lacks many of the patented features. (Trial Tr. vol. 5, 939-43, July 13, 2012.) These missing features include: (1) an actuation tube positioned about a

vibration coupler;[16] (2) camming members to drive clamp movement;[17] (3) a rotation mechanism for the shaft, blade and clamp;[18] (4) tissue engaging stops placed on the clamp member;[19] and (5) designing the device so it is able to fit down a 5 mm trocar.[20] Not only does Davison lack these features, but Ethicon failed to demonstrate by clear and convincing evidence that any of the additional prior art provides the missing features in a manner that would provide one of ordinary skill in the art with a reasonable expectation of success.

(a) The Combination Of References Do Not Provide Rotation For Purposes Of The Claimed Ultrasonic Device

Claims 1, 5, and 9-12 of the '050 patent, claims 1, 6, and 12-13 of the '286 patent, and claims 10-12 of the '544 patent require a rotation mechanism in an ultrasonic shears device that permits the shaft, blade, and clamp to rotate about the instrument's longitudinal axis by turning a rotation knob located adjacent the handle assembly. As Dr. Cimino admitted, Davison does not teach this feature. (Trial. Tr. vol. 5, 940, July 13, 2012.) In fact, Davison actually teaches away from the rotation feature used in the patents-in-suit. (Trial Tr. vol. 9, 1797-98, July 26, 2012.)

Yet Ethicon's purported obviousness case was nothing more than to point to references with a rotation knob, without any support for why or how such feature could be combined with Davison with a reasonable expectation of success. (*See* Trial Tr. vol. 5, 946, July 13, 2012 ("So, 315 also has a knob for rotating the jaw system . . . ."); *id*. at 947-48 referring to Robinson ("It has a rotation knob to rotate the jaws."); *id*. at 949 referring to Tovey ("[A]nd it shows . . .the ability to rotate the end effectors for a non-ultrasonic instrument . . . .").) When asked how one could use the knobs from these non-ultrasonic mechanical devices, however, Dr. Cimino could

[16] DTX 2437 at slides 44-52 ('050 patent claims 1, 5, and 9-12); *id*. at slides 64-75 ('286 patent claims 8-14).
[17] *Id*. at slide 52 ('050 patent claims 11 and 12); *id.* at slides 64-75('286 patent claims 8-14); *id*. at slides 81-106 ('544 patent claims 1-3, 6, 8-13, 16, 18, 23-25).
[18] *Id*. at slide 44 ('050 patent claims 1, 5, and 9-12); *id*. at slide 56 ('286 patent claims 1, 6, and 12-13); *id*. at slides 93, 95 ('544 patent claims 10-12).
[19] *Id*. at slides 58, 61 ('286 patent claims 6 and 7); *id*. at slide 104 ('544 patent claims 23 and 24).
[20] *Id*. at slide 102 ('544 patent claim 18).

only offer: "It's just a question of which things you want to rotate with the knob and you can mechanically couple them and rotate the whole system." (*Id.* at 953.) He provided no explanation of how one would implement the rotation in an ultrasonic device or how one skilled in the art would overcome the design challenges that such a combination would entail.

Yet, as Dr. Durfee explained in his rebuttal testimony, each of the cited non-ultrasonic references simply fail to account for the technical challenges faced in trying to implement full rotation in an ultrasonic shears device. (Trial Tr. vol. 9, 1797-807, July 26, 2012.) None of these references account for rotation when a central vibration rod is present or how it would provide the rotation required by the patents-in-suit. (*Id.*) For example, with regard to EP 315, Dr. Durfee explained, "if you connected that rod to the clamp, then as you turn knob 15, then the whole Davison instrument would rotate along with you. So, that's not going to work . . . ." (*Id.* at 1801.) Similarly, he explained with Robinson, "if you were to connect knob 120 to the clamp rod of Davison and then you spun 120, then the whole Davison instrument would turn." (*Id.* at 1803; *see also id.* at 1806 regarding Tovey: "[Y]ou couldn't take knob 124, just attach it to the clamp rod of Davison because if you twisted 124 the whole Davison instrument would rotate.")

Ethicon's cursory and hindsight driven obviousness contentions also are contradicted by the substantial evidence in the record. UltraCision engineer John Wright testified that factors in the decision not to include rotation in the LCS 10mm device (*i.e.*, the commercial embodiment of the Davison patent) were the "complexity of implementation" of rotation, as well as "complexity of design effort, design risk, [and] time to market." (Trial Tr. vol. 8, 1507, 1516, Dec. 12, 2007.) The U.S. Surgical and Misonix inventors expressed similar views. Mr. Mastri explained that rotation could not be easily transferred from a non-ultrasonic device because "it wasn't a simple thing as just taking an existing rotating mechanism, it had to be designed and developed

specifically for this device." (Trial Tr. vol. 1, 129-30, Dec. 3, 2007.) Misonix inventor Ronald Manna elaborated on the difficulties:

> When you implement rotation in a device like this, everything has to be locked together . . . otherwise you could transmit ultrasound energy . . . . So you need to lock everything together in respect to each other, such as the jaw to the blade, the blade to the handle, and at the same time have that entire assembly, the ultrasonic blade, the jaw mechanism, the tube and the ultrasonic transducer, rotate in concert.

(Trial Tr. vol. 3, 384, Dec 5, 2007.)

Given the substantial evidence in the record that implementation of rotation is not simply "a question of which things you want to rotate" as Dr. Cimino summarily concluded, his testimony cannot meet the clear and convincing burden to demonstrate that the rotation feature is obvious. *See Upjohn Co. v. Mova Pharm. Corp*., 225 F.3d 1306, 1311 (Fed. Cir. 2000) ("At this critical point in the determination of obviousness, there must be factual support for an expert's conclusory opinion."). Accordingly, Ethicon has failed to prove by clear and convincing evidence that the combination of prior art references render obvious any of claims 1, 5, and 9-12 of the '050 patent, claims 1, 6, and 12-13 of the '286 patent, and claims 10-12 of the '544 patent.

(b) The Combination Of References Do Not Teach The Ability To Fit Device Down A 5 mm Trocar Or The Claimed Tube-Within-A-Tube Design

Claims 1, 5, and 9-12 of the '050 patent and claim 8-14 of the '286 patent require an actuation tube positioned within the outer tube and positioned (the tube-within-a-tube design) about a vibration coupler. Claim 18 of the '544 patent requires designing the device so it is able to fit down a 5 mm trocar. Based on the record evidence at trial, Ethicon has failed to show that the claimed ultrasonic shears device with these features would be obvious.

Dr. Cimino offered only perfunctory testimony on these features. He simply identified these elements in the prior art absent any apparent reason to combine them with the features of

an ultrasonic device. For example, Dr. Cimino only offered: "[Robinson] also uses an actuator tube, or a tube-in-tube design." (Trial Tr. vol. 5, 947, July 13, 2012.); "The 662 . . . specifically describes an actuator tube-within-a-tube design." (*Id.* at 950); "[A]rt, whether it's Robinson or 315, both of those patents have slidable actuator tubes." (*Id.* at 952). Dr. Cimino provided no explanation how these features from stapling devices or a mechanical surgical jaw would be implemented with an ultrasonic device that has a vibration coupler down the center of the device. (*See id.* at 1021-22.) He also failed to provide any rationale as to why one of ordinary skill in the art would have a reasonable expectation of success with such combinations.

Indeed, the evidence of record indicates that combining a tube-within-a-tube mechanism with an ultrasonic vibration coupler would not be an obvious combination. For example, UltraCision engineer Gary Whipple agreed that it would be a "'big challenge' for [the 5 mm shears] project because these existing devices did not provide the possibility of putting an ultrasonic blade down the middle, they all had the middle filled with something else . . . ." (Trial Tr. vol. 8, 1379, Dec. 12, 2007.) U.S. Surgical inventor Dominick Mastri agreed, testifying that for a 5 mm shears device, "structurally, it was impossible to run things down the center of the device because of the reduced size." (Trial. Tr. vol. 1, 127, Dec. 3, 2007.) He further explained, "[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." (*Id.*)

Similar testimony evidences the nonobviousness of the feature to fit down a 5 mm trocar. Mr. Mastri testified that there "was not" any guidance in the field that showed how to implement a 5-millimeter design. (*Id.*) Ronald Manna explained: "[T]here is some significant hurdles that have to be overcome if you want to scale down a device to 5-millimeter." (Trial Tr. vol. 3, 382, Dec. 5, 2007.) Dr. Davison – named inventor of the Davison patent – acknowledged that despite

clear surgeon preference for 5 mm device versus 10 mm, UltraCision developed and launched a 10 mm "because [they] were concerned about the engineering and technical risks associated with bringing it down to 5 millimeters" (Trial Tr. vol. 7, 1327-28, Dec. 11, 2007.)[21]

Ethicon's attempt to point to the Sonosurg device as somehow evidencing obviousness of the tube-within-a-tube and 5 mm trocar size features is misguided. The Sonosurg was not asserted as prior art, and notably, Ethicon points to no evidence that this device even existed at the time of the inventions of the patents-in-suit.

Thus, the evidence shows that Ethicon failed to prove by clear and convincing evidence that the combination of prior art references render obvious any of claims requiring rotation.

4. The Tissue Stops Of The Asserted Claims Are Not Obvious

Ethicon's argument that the claims requiring tissue stops are obvious is also without merit. Davison does not disclose tissue stops on the clamp as required by the asserted claims. (Trial Tr. vol. 5, 982, July 13, 2012.) Ethicon's only purported support is a cursory comment by Dr. Cimino that "tissue stops being formed by the outer tube versus having them present on the jaw to me is an insubstantial difference." (*Id*. at 942-43.) This unsupported comment cannot constitute clear and convincing evidence. *See Upjohn*, 225 F.3d at 1311 ("in the determination of obviousness, there must be factual support for an expert's conclusory opinion.").

5. The Combination Of UltraCision/Ethicon Prototypes And Davison Do Not Provide The Features Of The Asserted Claims

(a) The Prototypes Are Not Prior Art And Cannot Be Used For Obviousness

As Ethicon's expert admitted, the prototypes and drawings on which he relied as purported "prior art" are not published documents. (Trial Tr. vol. 5, 1014-15, July 13, 2012.)

[21] *See also* Trial. Tr. vol. 3, 582, Jul. 11, 2012 (Dr. Gallagher: "[T]here wasn't appreciation of the complexity of decreasing the size of the shears . . . ."); Michetti Dep. 171:21-24, Dec. 15, 2005 (Ethicon engineer Michetti agreeing with excerpt from The Ethicon Endo-Leader (DTX 1586) that stated "[s]limming down the Harmonic Scalpel was more than a matter of scaling down the shaft diameter.").

They are not and have never been publicly available. Thus, to use these prototypes as prior art for purposes of obviousness, Ethicon must surmount two hurdles – and fails to do so.

First, Ethicon must demonstrate by clear and convincing evidence that the prototypes are prior art. "Secret prior art," *i.e.*, an alleged prior invention under §102(g), is not available as prior art for purposes of obviousness unless it satisfies all of the requirements of 35 U.S.C. § 102(g). *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1445 (Fed. Cir. 1984); *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir. 1988). "[P]roof of a conception alone does not suffice to establish [] work as prior [art]" for purposes of obviousness. *Kimberly-Clark*, 745 F. 2d at 1445. The work must be reduced to practice for its intended purpose. *Id.* As set forth in Tyco's JMOL No Invalidity, Ethicon failed to meet its clear and convincing burden that the prototypes qualify as prior art under § 102(g).

Second, even if Ethicon could *en arguendo* have surmounted this hurdle, for the reasons set out below, Ethicon has failed to prove by clear and convincing evidence that the combination of the prototypes with Davison renders the claims obvious.

(b) The Combination Of The Prototypes And Davison Does Not Render The Curved Blade Claims Obvious

Ethicon's theory that the blades from the Davison '055 patent in combination with the prototypes renders the curved blade claims (claim 15 of the '286 patent and claims 6 and 8 of the '544 patent) obvious also does not meet the clear and convincing standard.

Dr. Cimino pointed to Figures 8g, 8q, and 8p from the Davison patent as disclosing curved blades. (*See e.g.*, Trial Tr. vol. 5, 920-21, July 13, 2012.) The blade shown in Figure 8g from Davison, however, is simply a cylindrical blade and is not a curved blade for the reasons set forth in the Court's summary judgment ruling. *Tyco II*, 514 F. Supp. 2d at 381-82. With regard to the remaining two drawings, these figures of Davison fail to provide sufficient guidance to one

of ordinary skill in the art to arrive at the claimed invention. Figures 8q and 8p do not show these blade surfaces mated with an operable clamp as required for all the curved blade claims. (PTX 21 at EES0079133; *see also* Trial. Tr. vol. 9, 1760-62, July 26, 2012.) In Figure 8q there is no clamp arm at all and the clamp shown in Figure 8p would not be operable. (Trial Tr. vol. 9, 1761, July 26, 2012.) The deficiencies in Davison are compounded by the fact that the patent does not point to either of figures 8p or 8q as a preferred embodiment or otherwise draw attention to these variations. In fact, the United States Patent and Trademark Office considered Davison in the prosecution of the asserted curved blade claims and allowed the claims, despite the presence of the two figures with the curved blade in Davison. (PTX 52 at 2; PTX 53 at 2.)

Ethicon's attempt to conflate its obviousness case with its misplaced attacks on the enablement of the patents-in-suit is nothing more than smoke and mirrors. Enablement is a separate issue, dependent on different evidence. What is at issue here, is whether Ethicon has shown by clear and convincing evidence that one of ordinary skill in the art would have had an apparent reason to combine the curved blade features of Davison and do so with a reasonable expectation of success. Ethicon comes up empty-handed on this issue. The only testimony to which it points is from Dr. Amaral, not even from its own technical expert who offered no explanation as to how the blades of Davison would work with the prototypes. Moreover, even Dr. Amaral's purported statement is contradicted by his full testimony on the matter. Dr. Amaral expressed confusion when asked about the Davison disclosure, remarking: "[A]ll it shows is that there is a small hole here . . . . I couldn't tell you more than that" and "[t]he challenge was keeping this from breaking." (Trial Tr. vol. 9, 1565-66, Dec. 13, 2007.) Dr. Amaral also confirmed the patent does not "show or teach how to keep it from breaking." (*Id*. at 1566.)

Accordingly, Ethicon has failed to show by clear and convincing evidence that claim 15

of the '286 patent and claims 6 and 8 of the '544 patent are obvious.

(c) The Claimed Dual Cam Features Are Not Obvious

Ethicon's motion does not address the purported obviousness of all of the camming features but only those requiring dual cams (claims 11 and 12 of the '050 patent and claim 3 of the '544 patent.) Notably, Ethicon could not point to any prior art references or patents that contain a dual camming mechanism of the type claimed in the patents-in-suit.

The UltraCision and Ethicon prototypes have a single tab design, not a dual camming mechanism. (Trial Tr. vol. 5, 895, July 13, 2012.) Contrary to Ethicon's attempt to characterize the dual cams as "a trivial modification," Ethicon's own repeated attempts and failures, replete in the record, provide persuasive evidence of nonobviousness of this feature. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012) (describing defendant's failure to attain a feature lacking in the prior art as "classic evidence of nonobviousness."); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) (finding "repeated failures to design the claimed invention" to be "persuasive evidence that the [asserted patent] is nonobvious"). Certainly if a dual camming mechanism had been such an insignificant adjustment, it would not have taken Ethicon such a lengthy period of experimentation to arrive at this design.[19] Yet Ethicon struggled over a period of almost two years to reach the conclusion that the single-tab design was not workable.

Moreover, when Ethicon eventually discarded the single tab prototypes following its failed testing, the dual camming mechanism was not an immediate next choice. Ethicon halted the project in July 1997 and reviewed 40 different ideas for clamp arm design. (Trial Tr. vol. 10, 1766-67, Dec. 17, 2007.) According to a July 21, 1997 Ethicon memorandum, the project "[had] been placed on hold" and a "redesign of the blade is required" which "may need some

[19] *See* Tyco's JMOL No Invalidity at 18-19, ECF No. 210.

extraordinary efforts . . . to make this project happen." (PTX 24 at JAS000022.) By July 29th, 1997, Ethicon was still considering 38 clamp arm designs. (Trial Tr. vol. 10, 1767, Dec. 17, 2007; DTX 1401 at EES0073317). It was not until later that summer that a new clamp arm (allegedly having a pair of slots and camming members similar to the accused products) was built. (Trial Tr. vol. 10, 1766-67, Dec. 17, 2007.)

The evidence confirms that the redesign from a smaller to a larger blade impacted overall design, particularly the mechanisms by which the clamp would be actuated, thus underscoring that the differences between the single tab and the pair of cams was not trivial or insignificant as Dr. Cimino claims. (*See e.g.*, Trial Tr. vol. 4, 543, 546, 592, Dec. 6, 2007; Michetti Dep. 86:8-11, Dec. 15, 2005;[20] Goheen Dep. 131:1-14; Trial Tr. vol. 9, 1768-69, July 26, 2012.) As Dr. Durfee summarized: "So, if it was so obvious to go from the single tab to a dual cam you wouldn't expect them to go through that struggle, at least in the summer of 1997, to figure out how to get this clamp to work." (Trial Tr. vol. 9, 1769, July 26, 2012.)

Ethicon's reliance on alleged "simultaneous invention" in its motion as its sole support for obviousness of dual cams is inapt. "In some rare instances, the secondary consideration of simultaneous invention might also supply 'indicia of obviousness.'" *Geo M. Martin Co. v. Alliance Mach. Sys. Int'l, LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010). However, "[c]ontemporaneous independent invention may not alone show obviousness." *Monarch Knitting*, 139 F.3d at 883. Ethicon must show a trend in the prior art that evidences that the claimed invention as a solution to a recognized problem would be the product of ordinary skill in the art. *See Geo M. Martin*, 618 F.3d at 1305-06 (simultaneous invention coupled with similar devices evident in prior art); *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, No. 12-00630, 2012 WL 2572037, at *28 (N.D. Cal. Jul. 1, 2012) ("[T]he Federal Circuit [in *Geo M. Martin*] emphasized

[20] Designated as read-in testimony for the record, July 27, 2012.

that the evidence of a near-simultaneous invention was coupled with strong evidence of obviousness based on [other references].") (citation and quotation omitted). Accordingly, Ethicon failed to demonstrate by clear and convincing evidence that the dual cam claims of the patents-in-suit are obvious.

6. Secondary Considerations Are Highly Probative Evidence For The Non-Obviousness Of The Patented Features

An obviousness analysis must include consideration of any relevant objective evidence of obviousness or non-obviousness, or the so-called secondary considerations. *KSR*, 550 U.S. at 406. Secondary considerations, particularly commercial success, are highly probative here. *See Vulcan Eng'g Co. v. FATA Aluminum, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002) ("The commercial response to an invention is significant to determinations of obviousness, and is entitled to fair weight.") (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988)); *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000) (commercial success includes sales of the infringing product). Since the launch of the curved blade shears in early 2000, Ethicon has sold over 2 billion dollars worth of the accused products. (Trial Tr. vol. 6, 1061-62, July 23, 2012.) Ethicon has acknowledged the accused products are commercially successful. (Sokany Dep. 54:14-23, June 6, 2006;[22] PTX 42 at EES0248802.)

Ethicon marketing and sales training literature indicates that the commercial success of its ultrasonic shears devices is due to the patented features of the product, such as rotation, a curved blade, and the ability to fit the device down a 5 mm trocar (made possible by the patented tube-within-a-tube actuation and cam mechanism design). (PTX 42; PTX 47; *see also* Khadr

[22] Designated as read-in testimony for the record, July 27, 2012.

Dep. 54:25-55:3, June 2, 2006.)[23] Ethicon's curved blade products outsell its straight blade products by a ratio of 10-15 to 1. (Khadr Dep. 40:19-20.)[24]

In sum, the record evidence demonstrates that Ethicon has not met its burden to prove that the asserted patents are obvious by clear and convincing evidence.

D. Tyco Established Demand For The Patented Features And Is Entitled To Lost Profits

There is no dispute between the parties that a patentee can recover its "lost profits" as damages to compensate for the additional profits that it would have made "but for" the accused infringer's infringement. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). As set forth in Plaintiffs' Supplemental Proposed Conclusions of Law (ECF No. 170, Attachment 07, ¶¶ 69-70) (hereinafter "Tyco's SPCOL"), to get lost profits as actual damages, Tyco must demonstrate that there was a reasonable probability that, but for the infringement, it would have made Ethicon's sales. *State Indus. Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983) (recognizing that the patentee's burden is "not an absolute one, but rather a burden of reasonable probability.").

To be entitled to recover lost profits, the patentee must prove: (1) demand for the patented product; (2) absence of acceptable noninfringing substitute products; (3) the patentee possessed the manufacturing and marketing capability to exploit the demand; and (4) the amount of profit the patentee would have made. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

Ethicon asserts that Tyco is not entitled to lost profits due to its failure to make out a

[23] Designated as read-in testimony for the record, July 27, 2012.
[24] Additional secondary considerations evidence include industry praise of the curved blade feature (PTX 42 at EES0248820), unexpected results of faster cutting that resulted with the curved blade (PTX 47 at EES01615128; PTX 42 at EES0248809), and satisfaction of a long felt – but unmet need (Khadr Dep. 42:18-20).

prima facie case of demand for the features of the patents-in-suit. (Ethicon Br. at 26.) This argument rests on faulty legal premises and a blatant disregard of the overwhelming record evidence supporting demand for the patented features. The relevant and undisputed evidence submitted in Tyco's case-in-chief establishes that Tyco has made more than a prima facie showing that the patented features drive demand for the patented products and that it is indeed entitled to lost profits.

1. The Evidence Submitted In Tyco's Case-In-Chief Establishes Demand For The Patented Features And Ethicon's Motion Should Be Denied

As noted in Tyco's SPCOL (ECF No. 170, Attachment 07, ¶ 73) the demand factor "does not require any allocation of consumer demand among the various limitations recited in a patent claim." *DePuy Spine, Inc. v. Medtronic Sofamore Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009). In addition, where the patent owner and the infringer sell substantially the same product, evidence of sales of an infringing product generally represent evidence of consumer demand for the patented product. *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218-19 (Fed. Cir. 1993); *Boston Sci. Corp. v. Cordis Corp.*, 838 F. Supp. 2d 259, 273 (D. Del. 2012).

Contrary to Ethicon's position that "Tyco has not demonstrated that any of the [patented features] drive demand in laparoscopic cases," Tyco has more than satisfied its burden that the patented features drive consumer demand for the patented products. First and foremost, the evidence reveals that sales of the accused products are significant. (PTX 2427, Ex. E.) By March 31, 2012, Ethicon sold nearly 5.6 million units of the accused products and earned close to 2.1 billion dollars during this same period. (Trial Tr. vol. 6, 1061-62, July 23, 2012.) Under well-settled case precedent, the sales of the accused products are sufficient to establish consumer demand.

In addition, the record is replete with documentary and testimonial support that there is

demand for the patented features including curved blade, the ability to fit down a 5mm trocar, and rotation. For instance, concerning demand for curved blade, Ethicon's own witness James Haney, Ethicon's Director of Endo-Mechanical, Bariatric, and Metabolic Business, stated that sales of the straight blade decreased when the curved blade was introduced to the market. (Trial Tr. vol. 7, 1377-78, July 24, 2012; *see also* Trial Tr. vol. 1, 166, July 9, 2012; Trial Tr. vol. 6, 1100, July 23, 2012; Khadr Dep. 41:23-42:2, 42:11-22.) Dr. Gallagher, Ethicon's Clinical Research Director, when asked by the Court about customer demand for the ability to fit down a 5mm trocar, stated that the feedback for the introduction of the 5mm trocar was "really positive" and surgeons would be "very interested in this, it would be better to have a smaller instrument than the LCS-10 . . . there was a lot of excitement by surgeons who had seen it for the device." (Trial Tr. vol. 4, 735, July 12, 2012.) Even Dr. Bell, Ethicon's damages expert, stated that the ability to fit down a 5mm trocar is "a requirement, an expectation." (Trial Tr. vol. 7, 1408-09, July 24, 2012; *see also* Trial Tr. vol. 1, 166-67, July 9, 2012; Trial Tr. vol. 6, 1110-11, July 23, 2012.) Mr. Haney also stated that rotation is an expectation in laparoscopic procedures. (Trial Tr. vol. 7, 1321, July 24, 2012; *see also* Trial Tr. vol. 1, 166, July 9, 2012; Trial Tr. vol. 9, 1706-07, July 26, 2012; Khadr Dep. 54:25-55:3; Trial Tr. vol. 6, 1116-17, July 23, 2012; Trial Tr. vol. 7, 1408-09, July 24, 2012.)

Similarly, Ethicon's own marketing plans, sales training materials, and business plans repeatedly emphasize the value of the patented features. One of Ethicon's training documents reveals that the introduction of curved blade would "[m]eet market demand for curved shears." (DTX 1859 at EES0161609; *see also* DTX 1858; PTX 42; PTX 47; DTX 1857.) Similarly, in an internal Ethicon publication called "The Ethicon Endo-Leader," Ethicon touts its introduction of a 5mm device. The headline reads, "Market Demand Aligns EES Operations, Research and

Development, Manufacturing." (DTX 1586 at EES0266582.) The article goes on to note that "Surgeons loved the 10mm LCS so much, they asked for a smaller version and Ethicon Endo-Surgery, Inc. delivered. The LCS-5 is being introduced to a marketplace hungry to realize the benefits of precise cutting and coagulation for an increasing range of surgeries." (*Id.*; *see also* DTX 1858 at EES0161584; DTX 2372 at EES0161568.) Finally, there is also ample documentary support demonstrating demand for rotation. In an internal Ethicon memorandum regarding the value of roticulation, Ethicon specifically notes that "the issue of roticulation should be of significant importance to the Harmonic Scalpel," and that "roticulation consistently becomes the deciding factor for surgeons when forced to make trade-offs in product configurations." (PTX 43 at EES0168950; *see also* PTX 43.)[25]

Ethicon also appears to challenge Tyco's entitlement to recover damages on the entire value of the patented products at issue. (Ethicon Br. at 29.) As stated in Tyco's SPCOL, the "entire market value" rule is a typical method of fixing 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., Inc.*, 56 F.3d 1538, 1549 (Fed. Cir. 1995); *TWM Mfg. Co., Inc. v. Dura Corp.*, 789 F.2d 895, 901 (Fed. Cir. 1986) ("The entire market value rule allows for the recovery of damages based on the value of an entire apparatus containing several features, when the feature patented constitutes the basis for customer demand."); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 382 F.3d 1367, 1372 (Fed. Cir. 2004). It can be applied either to calculate lost profits or reasonable royalties. *See TWM*, 789 F.2d at 900-01.

Here, there is no dispute that the unpatented and patented components of the relevant

[25] Contrary to Ethicon's statements that Tyco does not claim that tissue stops, dual cam, and tube-in-tube construct drive demand, Tyco has made abundantly clear that these features enable the ability to fit down a 5mm trocar and thus drive demand for the product. (Trial Tr. vol. 6, 1117-18, July 23, 2012.)

products together constitute a single functional unit. Moreover, the evidence establishing demand for the patented features demonstrates the sound economic connection between the accused product's desirability and the patented features and thus also establishes basis for customer demand.

In summary, there is overwhelmingly documentary and testimonial evidence in the record establishing demand for the patented features and supporting Tyco's entitlement to recover damages based on the sale of the entire accused products.

E. Tyco Is Entitled To A Royalty Rate of Twelve Percent

A reasonable royalty is the minimum measure of damages in a patent infringement case. *King Instruments v. Perego*, 65 F.3d 941, 947 n.2 (Fed. Cir. 1995). It stems from a hypothetical negotiation between the patentee and the infringer when the infringement began. *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868-69 (Fed. Cir. 2010). To determine the amount that would have been set in such a hypothetical negotiation, courts focus on a number of factors first articulated in the seminal *Georgia-Pacific* decision. *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). The *Georgia-Pacific* factors are "[a] comprehensive (but unprioritized and often overlapping) list of relevant factors for a reasonable royalty calculation." *ResQNet.com*, 594 F.3d at 869.

Without providing any analysis of the *Georgia-Pacific* factors, Ethicon asserts that Tyco is not entitled to a reasonable royalty rate of twelve percent because it "did not perform a claim-by-claim analysis or regression analysis to show the impact that each individual feature of the patents-in-suit would have on the royalty rate." (Ethicon Br. at 30.) As stated above, the entire market value rule allows for the recovery of damages based on the value of an entire apparatus containing several features, when the feature patented constitutes the basis for customer demand. *TWM Mfg.*, 789 F.2d at 901. Consequently, Tyco is not required to conduct a claim-by-claim

analysis or regression analysis to demonstrate its entitlement to a twelve percent royalty. Indeed, Tyco has done what it is required to do under case precedent – an application of the *Georgia Pacific* factors – and has demonstrated the reasonableness of a twelve percent royalty rate.

F. Tyco Proved That Ethicon Willfully Infringed

Ethicon's motion for judgment as a matter of law of no willful infringement should be denied. Based on the trial record, there is clear and convincing evidence upon which the Court should readily deem Ethicon to be a willful infringer. Ethicon "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent" and Ethicon knew or should have known of the risk. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*).

The evidence demonstrates that Ethicon acted "in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known." *Id.* The Court's summary judgment ruling of infringement of the '050 and '286 patents objectively establishes that no reasonable fact finder could conclude Ethicon does not infringe. *See Tyco II*, 514 F. Supp. 2d at 383. Ethicon also conceded infringement as to the newly accused ACE products that it launched *after* the ruling of infringement. (*See* Stipulation and [Proposed] Order, *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 10-0060 (D. Conn. Feb. 4, 2011), ECF No. 59.) Yet even after the Court's summary judgment ruling 2007 and again in 2011 after Ethicon's stipulation, Ethicon has continued to sell its infringing products while maintaining its implausible position that such infringement is not willful.

This high risk of infringement was apparent to Ethicon since the issuance of the '286 patent in 2002. Verne Kreger, in-house counsel for Johnson & Johnson, testified that Ethicon was aware of issues of infringement shortly after the '286 patent issued, but nonetheless continued to sell infringing products. (Trial Tr. vol. 9, 1685-87, July 26, 2012.)

Ethicon knew of the risk it was taking. By late 2002, Mr. Kreger advised the business of a need for redesign of the products, to acquire a license, or to get an opinion of outside counsel. (*Id.* at 1685-86, 1706.) Yet Ethicon did not heed this advice. For example, although Ethicon considered designing around the claimed rotation feature, it declined to adopt the design around because of market demands and continued to sell infringing products with the rotation feature. (*Id*. at 1706-07.) Ethicon did not approach any outside counsel until early 2003, and even at that time did not request an opinion. (*Id*. at 1696-97.) Ethicon did not obtain an opinion of counsel until June 2004 – two years after becoming aware of potential infringement issues. Yet during this period of time, Ethicon still continued to sell its infringing products. While Ethicon pointed to the fact it revoked clearance to release a longer version of the LCS-C5 product, it still continued to sell the initially infringing LCS-C5 products. (*Id.* at 1687-88.) As Mr. Kreger acknowledged, Ethicon "basically [took] the risk it may be found to infringe." (*Id.*)

Ethicon's argument that it relied on its invalidity opinions is of no avail. Ethicon's primary defense in this trial has been that it had an alleged prior invention under 35 U.S.C. § 102(g). Yet not one of the invalidity opinions Ethicon relies upon, which Ethicon waited almost two years to obtain, include an invalidity defense under 102(g). (*Id*. at 1709.) Furthermore, as Mr. Kreger confirmed, Ethicon did not feel it could rely upon the prototypes as a foundation for a 102(g) defense. (*Id*. at 1660.)

Moreover, as the record has shown both prior to trial and at trial, the UltraCision and Ethicon prototypes do not constitute prior art. On summary judgment, the Court found that the "the UltraCision/Ethicon prototypes were not capable of fulfilling the function for which they were designed." *Tyco II*, 514 F. Supp. 2d at 361 (citation and quotation omitted). The Court's analysis in its ruling objectively confirmed that Ethicon is not justified in relying on its 102(g)

defense as a basis for no willfulness. *Id.* at 362. Accordingly, the Court's rejection of Ethicon's 102(g) arguments, coupled with its concurrent ruling of infringement as to all of Ethicon's then accused products, supports a finding of willful infringement.

Furthermore, the trial record provided no further support for Ethicon's reliance on its 102(g) defense. Ethicon failed to meet the high clear and convincing evidentiary burden required to prove that Ethicon had a prior conception, that it was able to reduce such prior conception to practice, or that it was sufficiently diligent in doing so. (*See* Tyco's JMOL No Invalidity.) Therefore, this defense is not reasonable.

Even if the Court were to find that Ethicon's prior invention defense was sufficient to negate a high likelihood of infringement – which it is not – Ethicon's defense does not apply to all of the claims for the asserted patents, namely the claims requiring dual cams and a curved blade, which fall outside Ethicon's purported defense.[26] Notably, Ethicon was already found to have infringed a curved blade claim on summary judgment. *Tyco II*, 514 F. Supp. 2d at 374-75. With regard to the camming member claims, the Court specifically found prior to trial that "a full trial record is required before a determination can be made as to whether Ethicon's non-infringement defense [of no cam mechanism] is reasonable." (Ruling on Motion for Partial Summary Judgment at 21, *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, No. 10-00060 (D. Conn. Sep. 23, 2011), ECF. No. 91.) Now that the trial record is complete, the evidence confirms that the accused products have a pair of camming members and pair of cam slots.[27] The record clearly establishes there is a high likelihood that the accused products infringe the asserted patents and that Ethicon was aware, or should have been aware, of the risk of infringement.

[26] *See* Tyco's JMOL Infringement at 3, ECF No. 211.
[27] *See* Tyco's JMOL Infringement at 4-9, ECF No. 211.

G. Tyco Is Entitled To A Permanent Injunction

Pursuant to Title 35, Section 283, "[t]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. In accordance with "well-established principles of equity," the Supreme Court prescribed a four-factor test that must be satisfied. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). To obtain a permanent injunction, Tyco 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. *Id*.

1. Tyco Has Suffered Irreparable Injury

Ethicon's argument that Tyco has not suffered irreparable harm because it has not previously sought a preliminary injunction is unavailing. (Ethicon Br. at 32-33.) The Federal Circuit has "never held that a failure to seek a preliminary injunction must be considered as a factor weighing against a court's issuance of a permanent injunction." *Mytee Prods., Inc. v. Harris Research, Inc.*, 439 F. App'x. 882, 888 (Fed. Cir. 2011) (rejecting infringer's characterization of patentee's decision not to seek a preliminary injunction as a "delay"). Ethicon – while criticizing Tyco's failure to seek a preliminary injunction – fails to point to any substantive evidence in the record to refute the overwhelming evidence that establishes the irreparable injury suffered by Tyco.

In considering whether or not a plaintiff has satisfied the irreparable injury prong of the *eBay* test, Courts have evaluated a variety of forms of injury. *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 983 (W.D. Tenn. 2006) (granting an injunction where, among

other things, the infringing sales had a "direct negative impact on sales of [patentee's] products protected by the [ ] patent, as well as on other [patentee] products"). Irreparable harm has been found where the plaintiff has established direct competition between the parties and a "loss in market share and access to potential customers" resulting from the defendant's introduction of infringing sales. *Robert Bosch LLC, v. Pylon Mfg. Corp,* 659 F.3d 1142, 1151 (Fed. Cir. 2011).

The evidence of record demonstrates that Tyco and Ethicon are direct competitors in the advanced energy market and that Ethicon's infringement has resulted in a significant loss in market share to Tyco. (*See* Trial Tr. vol. 7, 1332, July 24, 2012; PTX 582 at ETHI-24637.) Ethicon's own documents and witnesses establish that Ethicon viewed Tyco as a competitive threat. Indeed, Karim Khadr, Ethicon's Director of Global Development, confirmed that LigaSure was "a threat" to the Ethicon's vessel sealing franchise. (Khadr Dep. 97:17-22; *see also* DTX 1858 at EES161589; and PTX 41 at EES026004-05 ("Because AutoSonix is a direct competitor to the Harmonic Scalpel, its advantages are nearly identical to the Harmonic Scalpel."); Trial Tr. vol. 1, 177-78, July 9, 2012.)

Because Tyco and Ethicon are such fierce competitors, Tyco has suffered irreparable injury in connection with the erosion of the marketplace's perception of it as a leading innovator due to Ethicon's infringement of the patents-in-suit. Philip Roy, Tyco's Senior Director of Global New Product Energy Development, testified as to the impact the accused products have had on Tyco's reputation. He stated:

> [M]onetary damages obviously are something that is easily measured, it's something we can show on the slide with the revenues that were lost. Reputation is a different animal, and if you look at the world before 2000, before the launch of the curved shear with the infringing features, and you look at the world after, the perception of the two companies is significantly different. . . . U.S. Surgical, which was the former company, was seen as the pioneer of laparoscopic surgery, seen as an innovator, seen as a

> company that was at the front edge of driving changes in health care. . . . and with the launch of the ultrasonic franchise that became the Harmonic Scalpel, it changed the perception. It was a product that was able to get into hospitals that were committed Tyco hospitals, it gave them the air of innovation, and all that on our shoulders, all of that with our innovation, with our technology.

(Trial Tr. vol. 1, 178-79, July 9, 2012; *see also id*. at 210 ("I'm saying that the product line that's been infringing since notice was given has resulted in a change in perception that damaged our reputation because the marketplace was not aware that the technology they were embracing was not owned by Ethicon.").) In sum, there is overwhelming evidence of the irreparable harm suffered by Tyco as a result of Ethicon's infringement.

2. Monetary Damages Are Insufficient To Compensate For Injury To Tyco

Where a defendant's infringing acts result in losses of market share, brand recognition, and customer goodwill, such losses "may frequently defy attempts at valuation." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed.Cir. 2010). Here, it is impossible to accurately calculate the accused products' ongoing impact on Tyco's reputation as a leading innovator in the field, or measure the impact on Tyco's future market share. *Visto Corp. v. Seven Networks, Inc.*, No. 03-333, 2006 WL 3741891, at *4 (E.D. Tex. Dec. 19, 2006). Thus, monetary damages are inadequate to remedy Tyco's injury.

3. A Balancing Of The Hardships Weighs In Tyco's Favor

The balancing of hardships "assess the relative effect of granting or denying an injunction on the parties." *i4i Ltd. P'ship*, 598 F.3d at 862 (*citing eBay*, 547 U.S. at 391) (noting that several factors may be considered, including size of parties, products, and revenue sources). Courts have found a substantial hardship exists where the presence of infringing products causes a plaintiff to essentially compete against itself in the marketplace. *See Robert Bosch*, 669 F.3d at 1156.

Here, the balancing of hardships weigh in Tyco's favor. Without a permanent injunction, the presence of the accused products will continue to improperly skew the market. Contrary to Ethicon's representation of the potential hardship it could face should this Court grant a permanent injunction, Tyco merely seeks to enjoin Ethicon from selling products that infringe Tyco's patents. Accordingly, the scope of the permanent injunction sought by Tyco would not preclude Ethicon from introducing products that do not infringe Tyco's patents or continuing to market and sell its noninfringing products.

4. A Permanent Injunction Against Ethicon Would Not Disserve The Public Interest

(a) Public Policy Favors Scientific Innovation

"As a general matter, the public maintains an interest in protecting the rights of patent holders, and injunctions serve that interest." *Smith & Nephew*, 466 F. Supp. 2d at 985. When considering the final public interest element of the test, the Federal Circuit has "long acknowledged the importance of the patent system in encouraging innovation." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). In the field of medical research in particular, the public interest supports the grant of an injunction at least in part as an incentive to the companies to engage in costly research and development efforts. *Id*. at 1383-84.

Tyco's predecessor, U.S. Surgical, was seen as "a pioneer in developing surgical instruments for laparoscopic surgery." (Trial Tr. vol. 7, 1326-27, Dec. 11, 2007.) Accordingly, the public interest would be served by granting Tyco a permanent injunction because it would encourage Tyco's continued investment in developing innovative medical solutions.

(b) The Public Will Not Be Harmed By A Permanent Injunction Barring Sales Of The Accused Products

A court may issue a permanent injunction upon concluding there is no "sufficient objective evidence of a public health issue" in connection with the products at issue. *Acumed*

LLC v. Stryker Corp., 551 F.3d 1323, 1331 (Fed. Cir. 2008) (finding the district court did not abuse its discretion when assuming that "physicians could chose noninfringing alternatives to the [infringing device]"). Ethicon's reliance on *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates., Inc.*, is misplaced, because unlike the facts of this case, the plaintiff in *Bard* did not offer an alternative to one of the two infringing products in the marketplace. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-0597, 2009 WL 920300, at *4 (D. Ariz. Mar. 31, 2009). Here, the record clearly demonstrates that Tyco's available products can perform the same functions as the accused products. (Trial Tr. vol. 1, 142-44, July 9, 2011; *id.* at 211; Trial Tr. vol. 4, 782, July 12, 2012.) Indeed the parties have stipulated that Tyco has both the manufacturing and marketing capacity to fill any void resulting from selling the infringing products with comparable products. (Trial Tr. vol. 6, 1122, July 23, 2012.) Accordingly, permanently enjoining the sale of the accused products will not harm the public.

In summary, Tyco has demonstrated that it has suffered an irreparable injury for which monetary damages are inadequate, that the balance of hardships support injunctive relief, and that the public interest would not be disserved. Thus, Tyco is entitled to a permanent injunction.

IV. CONCLUSION

For the reasons set forth above, Tyco respectfully requests that this Court deny all motions for judgment submitted by Ethicon.

Dated: August 14, 2012

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2012, a copy of the foregoing document was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by email to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing.Parties may access this filing through the Court's CM/ECF System.

Dated: August 14, 2012

Respectfully submitted,

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