UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Tyco Healthcare Group, LP, *et al.*, *Plaintiff*s, *v.* Ethicon Endo–Surgery, Inc., *Defendant*.	Civil No. 3:10cv60 (JBA) September 23, 2011

RULING ON MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiffs Tyco Healthcare Group LP ("Tyco") and United States Surgical Corporation ("USSC") sued Ethicon Endo–Surgery, Inc. ("Ethicon"), claiming that Ethicon's Harmonic Scalpel and Harmonic ACE products infringe Tyco's patents. Among other claims for relief, Tyco seeks a declaration that Ethicon willfully infringed its patents, which would entitle Tyco to up to treble damages. Ethicon now moves for partial summary judgment of no willful infringement of the asserted claims of United States Patent Nos. 6,063,050 (the "'050 patent"), 6,468,286 (the "'286 patent"), and 6,682,544 (the "'544 patent"). For the following reasons, Defendant's motion for partial summary judgment will be denied.

I. Background

A. Procedural Background

Tyco earlier sued Ethicon in 2004 for infringement of the '050 patent, the '286 patent, the '544 patent, and Patent No. 6,280,407. Following claim construction, and discovery, the parties filed summary–judgment motions related to infringement, non–infringement, and invalidity of various claims of the four patents–in–suit. The Court granted Tyco's motion for summary judgment of infringement of claims 1, 5, and 9 of the '050 patent and claims 1, 6, 7, and 16 of the '286 patent; denied Ethicon's motion for summary judgment of

non–infringement with respect to claims 11–12 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 raised in its motion, except for two dependent claims, claims 17 and 19, from the '286 patent; and denied Ethicon's motion seeking to invalidate claims from each of the patents–in–suit based on its prior–invention defense under 35 U.S.C. § 102(g). The case proceeded to trial, and after the close of Tyco's case–in–chief, Ethicon moved for judgment as a matter of law on the issue of standing, which the Court granted and which was affirmed by the Federal Circuit. The Federal Circuit held that Tyco may be able to show in a subsequent action that it held title to asserted patents based on an intra–company "Contribution Agreement" between United States Surgical Corporation ("USSC") and Tyco, or otherwise, *see Tyco Healthcare Group LP v. Ethicon Endo–Surgery, Inc.* ("*Tyco III*"), 587 F.3d 1375 (Fed. Cir. 2009), and Tyco and USSC filed this action on January 14, 2010, asserting infringement by the same Ethicon products accused in the prior action as well as four additional Ethicon products that have come to market since dismissal of the earlier action, the ACE 23E, ACE 36E, ACE 45E, and Harmonic Wave products. The parties have stipulated that the Court's summary judgment ruling in the earlier action applies equally to the newly–accused ACE23E, ACE 36E, and ACE 45E products. (*See* Stipulation and Ord. [Doc. # 66].) The parties also stipulate that for purposes of this action, Defendant will not contest Plaintiff's claim of ownership of the patents–in–suit by virtue of the April 1, 1999 asset–transfer agreement. (*See* Stipulation [Doc. # 43].)

B. Technology

The patents at–issue relate to medical instruments that employ ultrasonic energy to cut and coagulate vessels in surgery. Ultrasonic surgical instruments were pioneered by

UltraCision and first brought to market in 1991. Ethicon purchased UltraCision in 1995 and, in 1997, introduced its first Harmonic Scalpel instruments primarily for use in lapraroscopic and endoscopic surgical procedures, which are techniques for performing surgical operations using instruments inserted through narrow, hollow tubes rather than using instruments in larger, open incisions, as in traditional surgery. (Cimino Report, Ex. 14 to Mem. Opp'n at 3.) Generally, in these instruments, ultrasonic energy vibrates a tool end very rapidly, "such that, when vibrating, it cuts tissue and provides hemostasis th[r]ough the generation of frictional heating between the vibrating tool and the tissue," which has the effect of "simultaneously provid[ing] precise cutting and seal[ing] off blood vessels to prevent bleeding." (*Id*. at 4.)

For the specific patents–in–suit, a generator is attached to a transducer that converts electrical energy into ultrasonic mechanical vibrations, which are translated down the shaft of the surgical instrument to a blade at the end of the device, which is thereby enabled to cut tissue and coagulate vessels with which it comes into contact. (*Id*. at 6–7.)

The parties agree that the Tyco inventors named on the patents–in–suit reduced the claimed inventions to practice no earlier than March 1997, and Ethicon contends that UltraCision, the company it acquired in November 1995, had several prototypes reduced to practice by March 1997 which Defendant continued to develop post–acquisition.

II. Discussion[1]

"To willfully infringe a patent, the patent must exist and [the accused infringer] must have knowledge of it." The Federal Circuit in *In re Seagate Technology, LLC* explained that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*) (overruling the "duty of care standard" for willful patent infringement announced in *Underwater Devices Inc. v. Morrison–Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983)).

"Reckless" is defined in common law as acting "in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known." *Id*. (citing *Safeco Ins. Co. Of Am. v. Burr*, 551 U.S. 47 (2007)). Thus, "to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent," but "[t]he state of mind of the accused infringer is not relevant" to this proof. *Id*. After satisfying this threshold objective standard, a plaintiff must then prove the subjective prong, "that this objectively–defined risk . . . was either known or so obvious that it should have been known to the accused infringer." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1335 (Fed. Cir. 2009).

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[1] "Summary judgment is appropriate where, construing all evidence in the light most favorable to the non-moving party," *Pabon v. Wright*, 459 F.3d 241, 247 (2d Cir. 2006), "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law," Fed. R. Civ. P. 56(c)(2). An issue of fact is "material" if it "might affect the outcome of the suit under the governing law," and is "genuine" if "a reasonable jury could return a verdict for the nonmoving party" based on it. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "Unsupported allegations do not create a material issue of fact." *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000).

Ethicon's motion focuses solely on the threshold objective prong and argues that the record lacks clear and convincing evidence that it acted despite an objectively high likelihood that its actions constituted infringement.[2] It advances affirmative defenses of invalidity and non–infringement, the reasonableness of which it claims demonstrates that Plaintiff cannot prove Defendant acted in an objectively reckless manner.[3] First, Ethicon maintains that its prior–invention invalidity defense is reasonable. Second, Ethicon argues that its accused products and the prototypes from which they derive lack a "cam mechanism," which 24 of the 31 claims asserted by Tyco require, such that its non–infringement defense is also reasonable, defeating claims of objective recklessness.

To prevail on its motion for summary judgment, Ethicon must therefore present an undisputed record showing that Ethicon's affirmative defenses were at least reasonable, even if not ultimately meritorious, meaning therefore, drawing all reasonable inferences in Tyco's

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[2] Thus, Ethicon argues that Tyco's evidence that Ethicon sought a license from Tyco on the patents–in–suit, researched possible "design–arounds," and continued to sell accused products that infringe asserted patents even after the Court's October 2007 infringement ruling bears on the subjective willfulness prong and not the analysis of whether Ethicon had objectively reasonable defenses.

[3] "Under this 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." *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 F.App'x 284 (Fed. Cir. 2008); *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1306, 1319–20 (Fed. Cir. 2010) ("The objective prong of *Seagate* tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement.").

favor, that Tyco cannot prove that Defendant's affirmative defenses were unreasonable, which it would be required to do to prove Defendant's wilfulness.

A. Prior Invention Defense

Ethicon contends that its defense of prior invention—predicated on its assertion that the invention recited in Tyco's patent claims was reduced to practice by Ultracision and/or Ethicon inventors prior to reduction to practice of the Tyco invention—was reasonable and thus, there was no objectively high likelihood of infringing Tyco's patents–in–suit. Section 102(g) of the Patent Act provides that "[a] person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it," and "[i]n determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the 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).

There is no dispute that UltraCision developed a prototype for the devices that allegedly infringe (the accused "LCS–5"), and after its acquisition by Ethicon, both engaged in significant testing. The parties disagree as to whether Ethicon reduced the LCS–5 to practice before March 1997, the earliest invention date for Tyco's claims and the measuring date for the willful–infringement analysis. The rule for determining priority of invention is that it "goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Monsanto Co. v. Mycogen Plant Science, Inc.*

(*Monsanto III*), 261 F.3d 1356, 1362 (Fed. Cir. 2001) (internal quotation omitted). To establish reduction to practice, a party must demonstrate

> (1) construction of an embodiment or performance of a process that me[ets] all of the limitations of the [relevant patent claim]; (2) [] that the invention would work for its intended purpose; . . . and (3) the existence of sufficient evidence to corroborate inventor testimony regarding these events.

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1169 (Fed. Cir. 2006) (internal quotations omitted); *see also Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1263 (Fed. Cir. 2002) (noting that "[c]onception must include every feature or limitation of the claimed invention"). The determination of "[p]riority of invention is a question of law based on underlying factual determinations" and "[b]ecause a patent is presumed valid, the quantum of proof required [is] clear and convincing evidence." *Monsanto III*, 261 F.3d at 1362.

In making "a section 102(g) priority determination between an issued patent and a scientist's work, the focus of the inquiry [is] upon the invention recited in the patent's claims." *Mycogen Plant Sci., Inc. v. Monsanto Co.* (*Monsanto II*), 243 F.3d 1316, 1332–33 (Fed. Cir. 2001). "It is important to distinguish between the goals of the project being pursued when the alleged reductions to practice were made and the objects of the invention of the count," because "[r]eduction to practice may occur [ ] without attaining the specific goals of the project." *Hradel v. Griffith*, 54 C.C.P.A. 911, 367 F.2d 851, 854 n.1 (1966). While "[i]t is not necessary for testing to have proceeded to the point where the device is ready for commercialization in order to have an actual reduction to practice, . . . there must be a relationship between the test conditions and the intended functional setting . . . and the tests must prove that the invention will perform satisfactorily in the intended functional setting." *Koval v. Bodenschatz*, 59 C.C.P.A. 1113, 463 F.2d 442, 447 (Cust. & Pat. App. 1972); *accord*

Scott v. Finney, 34 F.3d 1058, 1061 (Fed. Cir. 1994) ("Reduction to practice does not require that the invention, when tested, be in a commercially satisfactory stage of development."). Accordingly, "[t]esting need not show utility beyond a possibility of failure," but it must show "utility beyond a probability of failure." *Scott*, 34 F.3d at 1061 ("Reduction to practice . . . does not require actual use, but only a reasonable showing that the invention will work to overcome the problem it addresses."). Additionally, "the inventor must contemporaneously appreciate that the embodiment worked and that it met all the limitations of the [claim]." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed.Cir.1998).

Ascertaining the intended purpose of the claim includes consideration of the invention's specifications. *See, e.g.*, *Manning v. Paradis*, 296 F.3d 1098, 1103 (Fed.Cir. 2002); *Monsanto Co. v. Mycogen Plant Science, Inc.* (*Monsanto I*), 61 F. Supp. 2d 133, 192 (D. Del. 1999). Here, although "the claims at issue do not specifically claim an instrument that can coagulate (and cut) body tissue, . . . it appears undisputed that the functionality of such an instrument is severely impaired if it does not also facilitate coagulation," and therefore, "although not explicitly incorporated into each claim, the intended purpose of this invention, as stated in the patent abstracts and thereby implicit in the claims themselves, is to comprise '[a]n ultrasonic dissection and coagulation system for surgical use.'"[4] *Tyco*

[4] Ethicon discusses a "split in authority" in how courts determine an invention's intended purpose: some courts have found that a demonstration of "practical utility for *any* purpose," *see Fujikawa v. Wattansin*, 93 F.3d 1559, 1554 (Fed. Cir. 1996), is sufficient to show reduction to practice in cases where "no purpose is expressly stated," while other courts allow an invention's specifications to be considered in order to determine the intended purpose. (*See* Mem. in Support of Summ. J. [Doc. # 60] at 12.) *See also Shurie v. Richmond*, 699 F.2d 1156, 1159 (Fed. Cir. 1983) ("When . . . the intended use of an invention is not indicated in the count, evidence demonstrating substantial utility for *any* purpose is enough to show reduction to practice."). This case, however, does not present a situation

Healthcare Group LP v. Ethicon Endo–Surgery (Tyco I), Inc., 514 F. Supp. 2d 351, 360 (D. Conn. 2007). Therefore, as to its invalidity affirmative defense, Ethicon must demonstrate the absence of clear and convincing evidence that prior to March 1997, its prototypes could not successfully cut tissue and coagulate blood vessels beyond a probability of failure.[5]

Ethicon maintains that *Tyco I* did not foreclose the possibility that it could adduce evidence at trial that its prior art—one prototype developed by UltraCision, as well as two prototypes made by Ethicon after its acquisition of UltraCision—worked for their intended purpose, which it says it was "in the midst of proving when trial was halted in 2007." (Mem. Supp. at 13.) In *Tyco I*, although the Court recognized that Ethicon's prototypes pre–dated the earliest invention date for Tyco's claims (March 1997), it denied Ethicon's motion for summary judgment of invalidity under Section 102(g) because it was "not convinced that the testing reflected in the record shows 'utility beyond a probability of failure'" in meeting the twin–purposes of dissection and coagulation for surgical use, required to reduce to practice. *Tyco I* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)).

The question now is whether the entire summary–judgment record, which includes the earlier trial evidence, indisputably demonstrates an absence of clear and convincing evidence that Defendant's prototypes were unable to fulfill the intended purposes of dissection and coagulation; Ethicon maintains that evidence presented at trial demonstrates

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where the intended purpose of the invention at issue is not indicated in any way.

[5] Deciding whether Defendant has met its burden at the summary judgment stage of establishing that Plaintiff cannot prove by clear and convincing evidence the unreasonableness of Defendant's affirmative defenses, the merits of which Defendant would be required to prove at trial by clear and convincing evidence, seems—as Winston Churchill once described the actions of Russia in 1939—something of "a riddle, wrapped in a mystery, inside an enigma."

that the prototypes effectively cut and coagulated during preclinical tests on goats and pigs, while Tyco argues that the prototypes were never reduced to practice because they suffered serious shortcomings in coagulating blood vessels and caused smoke and charring. Ethicon relies primarily on the trial testimony of three witnesses, Dr. Thomas Davison, founder and former president of UltraCision, Dr. Joseph Amaral, the former president of Rhode Island Hospital who was involved in early testing on the prototypes, and Mark Tstonton, an Ethicon mechanical design engineer, who worked on the team tasked in June, 1996 with perfecting the UltraCision prototypes and preparing them for commercial launch (the "UT5.5 project"). In its opposition to Ethicon's motion for summary judgment, Tyco cites to the cross–examination testimony of these witnesses, and others, to show that the prototypes were not yet fit for their intended purpose.

Dr. Davison testified that between 1991 and 1993, he tested a ten–millimeter ultrasonic device (the "LCS–10") that included "tube–in–tube construction" as well as roticulation of the blade and clamp arm together, both of which were claimed in Tyco's subsequently–filed patents, and that the device was able to cut and coagulate during testing in an animal lab. (*See* Trial Tr., Ex. 10 to Mem. Supp. at 1294:1–1297:14.) He also testified that he tested the LCS–5, a five–millimeter UltraCision prototype in existence in 1995, which was based on the LCS–10, that was able to cut and coagulate "mesenteric tissue with the mesenteric vessels, to dissect out the gastropyloric artery, by first dissecting it out with the dissecting characteristics of the device, and then coagulating that artery, which was two or three arteries, and then dissect out the femoral artery, which was about 4–millimeter, cut and coagulate, and then the iliac artery, which was at least 5–millimeter, cut and coagulate that."

(*Id*. at 1305:3–21.) He further testified that UltraCision developed a curved–blade version of its prototype, which it developed, fabricated, and tested in a pig model.

In response, Tyco points out that Davison's testimony is uncorroborated by documentary evidence or lab reports, and in fact, Davison's testimony is contradicted by the 1998 President's Award submission, the accuracy of which was sworn to by Mark Tsonton. (Ex. 19 to Pl.'s Mem. Opp'n. [Doc. # 67].) There, the submission states, the "prototype LCS–5 caused tissue sticking, smoke production obscuring laparoscopic visualization, and undesirable thermal injury to tissues," and "Teflon clamp pads were melting, and in some instances, the blade itself melted." (*Id.*)

Dr. Amaral testified that he began a working relationship with Dr. Davison in 1990 and had an opportunity to use the prototype ultrasonic devices Dr. Davison was developing. Dr. Amaral explained that he used an LCS–5 prototype during early testing, and when asked whether it was able to cut tissue, he responded "[i]t worked just fine," and when asked whether it was able to coagulate blood vessels, he replied "[y]es." (Trial Tr., Ex. 11 to Mem. Supp. at 1544:9–14.) He further testified that at the time Ethicon acquired UltraCision in 1995, the LCS–5 "worked effectively, but my interpretation what was going on is that Ethicon was also trying to understand the technology," and as a result, "there was an iterative process going on," by which Ethicon tested variations on the prototype: "one might clamp better, one might grasp better, one might do this better," and Dr. Amaral was frustrated because "it worked right—it worked early, right when they bought it." (*Id*. at 1545:24–1546:14.) Dr. Amaral described, and Ethicon introduced a video recording of a successful test he performed on a goat using the LCS–5, with which he cut an infundibulopelvic ligament and coagulated blood vessels in it. (*Id*. at 1552:4–1557:7.) He

explained that as he was testing certain variations on the prototypes he may have commented that they did not grasp or coagulate well, because he was tasked with providing critical feedback on them, and "one might grasp . . . better, one might cut better, one might have a little more thermal damage, one might make a little bit more smoke. The idea was they all worked and they all could be released and we were just sort of playing around the edges of this." (*Id.* at 1557:23–1557:7.) He opined at trial that the various prototypes worked for their intended purpose before UltraCision's acquisition by Ethicon at the end of 1995. (*Id.* at 1568:7–20.) Dr. Amaral also believed that Ethicon's testing regime was "too rigorous . . . [;] the desired outcome on the tests that were being done were more than necessary for what one would do, one needed to work clinically," and "they were putting it to the highest possible standard, which wasn't necessary." (*Id.* at 1621:3–21.) However, on cross–examination, Dr. Amaral also conceded that if what was stated in the 1998 Award Submission was true, i.e., tissue sticking, smoke production, thermal injury to tissues, etc., that was a problem. (Amaral Tr., Ex. 24 to Pl.'s Mem. Opp'n at 1580:6–17.)

Tsonton was a member of the UT5.5 project focused on improving the prototype's manufacturability, ergonomics, and reduced part count, while maintaining the prototype's tube–in–tube design, its ability to be inserted into a five millimeter trocar, and the roticulation of the blade and clamp. (Trial Tr. at 1632:9–1657:2.) He kept detailed records on the progress made, including results of tests performed by Dr. Amaral and Dr. Laura Gallagher. Based on these records, Tsonton testified that during animal tests, the Ethicon prototypes performed "fairly well," although "[i]n some of the more difficult testing that we completed, they did have problems." (*Id.* at 1686:10–16.) He explained that the "requirements for the device were generally that it had to be a general utility device to be

used in laparoscopic surgery, so it had to be able to grasp tissue effectively, manipulate tissue effectively, and be able to cut and coagulate tissue effectively," (*id*. at 1686:17–24), and during testing, the prototypes could grasp, dissect, cut, coagulate, and seal vessels effectively (*id*. at 1686:24–1687:9). Tsonton acknowledged that the LCS–5 could not seal vessels as well as the larger, commercialized LCS–10 because "[t]he LCS–10 is a very robust device . . . [that] had been tuned and in the market for a long period of time and it also had the unique feature of having three different blade sides on it that you could use to do different functions, and the LCS–10 functioned better, especially in difficult models, than the 5–millimeter UT5.5 did"; however, the LCS–5 was able to seal small vessels as well as the LCS–10 did. (*Id*. at 1687:12–24.)

Tyco argues that Dr. Davison, Dr. Amaral, and Tsonton's testimony that the LCS–5 prototype successfully cut and coagulated small blood vessels notwithstanding, significant evidence was introduced during the earlier trial that the device was unreliable, in that it did not effectively seal large vessels and caused tissue sticking, smoke, and charring. Tyco relies heavily on the above–referenced "1998 President's Quality Award Submission" (the "1998 Award Submission") for the UltraCision shears prototype performance screening process team (Ex. 19 to Mem. Opp'n), which was central to the Court's denial of summary judgment on invalidity in *Tyco I*, 514 F. Supp. 2d at 361–62. The 1998 Award Submission states that although "[c]reation of an effective vessel seal was identified as the most critical clinical function of the LCS–5," as of November 1995, the "acquired 5mm Laparosonic Coagulating Shears (LCS–5) prototypes created poor vessel seals," by comparison to "the predicate device, the LCS–10." (Ex. 9 to Mem. Opp'n at 2–3.) The award also stated that "[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*. at 3.) Further, during lab testing, several doctors noted "bleeding during blood vessel transections, tissue sticking to the blade, tissue charring, excessive smoke production, and generator lockout." (*Id*. at 4.) While the LCS–10 incidence of hemorrhage was ten percent plus/minus nine percent, the "mean incidence of hemorrhage with the early LCS–5 prototypes was 67%." (*Id*.)

Tyco further notes that Dr. Davison testified that ultrasonic devices cause, at most, minimal smoke "much, much less than, 10, 20, 100 times less than electrosurgery" (Trial Tr. at 1293:22–1294:5), that with ultrasonic scalpel technology, "you are supposed to get little, if any, tissue charring" (*id*. at 1333:20–23), and that the LCS–5 in its initial testing as reflected in the 1998 Award Submission was unable to produce either of those two positive results. Dr. Amaral also agreed that if true, the above–described shortcomings with the LCS–5 noted in the 1998 Award Submission would amount to "problems with the device," (*id*. at 1574:9–1576:10), and he testified that he did once see "a blood vessel bleed" during testing and would comment on various perceived shortcomings. (*Id*. at 1578:24–1579:2.) He qualified the import of his statement by saying that "[t]he fact of the matter is, they were all in my mind . . . devices that worked." (*Id*. at 1579:2–4.) Tsonton recalled a laboratory test of a prototype performed by Dr. Amaral on a pig on September 19, 1996, during which Dr. Amaral had difficulty grasping tissue, the blade caused burning on the liver, and a cut was achieved without hemostasis. (Trial Tr., Ex. 20 to Mem. Opp'n at 1719:16–1721:2.) Tsonton also testified that "blade breakage" remained a significant issue with the Ethicon prototypes as of at least July 1997. (*Id*. at 1735:25–1736:6.)

Tyco emphasizes other trial evidence that called into question the progress of reduction to practice. For instance, it points to the testimony of Ethicon project engineer Greg Bishop that "I know we had a lot of issues with sealing vessels with the LCS–5" because it was a "hot device," and "[w]hen you go from a 10–millimeter device to a 5–millimeter device, you cut the mass down" such that "[t]he area is smaller, but you are still pumping the same amount of energy into a smaller mass," resulting in "the blade . . . run[ning] hotter, cut[ting] faster, burn[ing] and char[ring]." (Trial Tr., Ex. 35 to Mem. Opp'n at 524:7–18.) Ethicon's project–leader Rich Goheen also testified that although Ethicon intended to submit to the Food and Drug Administration ("FDA") its application for a Section 510(k) clearance for a new medical product for the LCS–5 in April 1997, Ethicon delayed its submission until January 1998 because as of February 1997, the prototype did not reliably coagulate vessels that were three millimeters in diameter, an important goal for Ethicon because it would "allow[] us to have the device used in the same procedures that the 10–millimeter LCS was used in." (Trial Tr., Ex. 22 to Mem. Opp'n at 51:14–54:7.) Dr. Gallagher, Ethicon's "preclinical study director" overseeing testing, acknowledged that as of the beginning of the second quarter of 1997, her "biggest concern was of creating an effective vessel seal[, a]nd we weren't doing that, and there wasn't enough understood about the technology and blade design and many other factors to understand why." (Gallagher Dep., Ex. 21 to Mem. Opp'n at 99:18–25.)

Ethicon counters that the 1998 Award Submission reflects "a laparoscopic abdominal hysterectomy being performed on a goat," and according to a Tyco corporate representative, hysterectomies present a "high likelihood of" of encountering a large vessel, one that is "of the caliber of 4 to 7 millimeters." (Philip Charles Roy Dep., Ex. 28 to Reply at 140:8–24.)

Ethicon represents that it chose the difficult goat model with larger vessels because it "closely represent[ed] tissue characteristics and vessel sizes in the human," and was therefore a proxy for testing the effectiveness in a human hysterectomy. (Ex. 34 to Def.'s Reply at DTX–1565–0027.)

Responding to the evidence presented during the earlier trial and in the current record, which raises factual questions as to how reliably the LCS–5 cut and coagulated vessels, Ethicon argues that there is no requirement that the devices were superior or equal to the prior art, or that they were incapable of improvement, and that its internal testing standards are not the relevant measure of whether the LCS–5 successfully cut and coagulated vessels. "Proof of the invention's utility for its intended purpose does not require proof of its flawlessness; it is only necessary to show that the invention is able to perform its intended purpose beyond a probability of failure." *Eastern Rotorcraft Corp. United States*, 384 F.2d 429, 431 (Ct. Cl. 1967.)

Ethicon is correct that the appropriate measure is "the objects of the invention of the count" and not "the specific goals of the project" undertaken by Ultracision and Ethicon. *Hradel*, 367 F.2d at 854 n.1. To that end, whether the LCS–5 coagulated large vessels as effectively as its predecessor the LCS–10 is less significant than whether the LCS–5 was reduced to practice as seen by its performance under test conditions which approximated "the intended functional setting," *Koval*, 463 F.2d at 447, i.e., surgery on humans, measured against the inventions in Tyco's claims, which were incorporated into the Tyco AutoSonix invention.[6] The testing Tyco conducted on its AutoSonix product for its application to the

[6] As explained in the Claim Construction in the earlier action, the '050 patent covers Tyco's ultrasonic scalpel "handle"; the '286 patent covers the "clamp member," which is

FDA for a Section 510(k) clearance to market a medical device was done only on "mesentery vessels," which are vessels "typically [] around less than 1 millimeter," as opposed to the larger four to seven millimeter vessels that presented difficulty for the LCS–5. (Trial Tr., Ex. 26 to Reply at 644:5–19; 650:25–651:9.) The testimony of Doctors Davison, Amaral, and Tsonton that the LCS–5 was able to cut and coagulate small blood vessels in tests on goats and pigs prior to March 1997—even though Ethicon continued to work on problems to enable the device to cut and coagulate larger vessels so that it could be used for the same procedures as the LCS–10—show that Defendant has some reliable evidence, of disputed weight and significance, that Ethicon had reduced the LCS–5 to practice before Tyco.

There remain questions of fact for trial on whether Ethicon's claim that it reduced the LCS–5 to practice before Tyco is a reasonably–maintained defense, given its documented shortcomings. The record shows that Ethicon might prevail on its invalidity defense, but whether the competing factual disputes are truly close calls, or just "close" because of unclear or equivocal evidence in the summary judgment record, cannot be determined at this stage. *See DePuy Spine, Inc.*, 567 F.3d at 1337 ("The jury could have reasonably found for either party on the question of equivalence. While the fact that an issue was submitted to a jury does not automatically immunize an accused infringer from a finding of willful infringement, the record developed in the infringement proceeding in this case, viewed objectively, indisputably shows that the question of equivalence was a close one, particularly insofar as equivalence requires an intensely factual inquiry. The mere fact that the jury

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adjacent to the cutting jaw and includes a pair of tissue–engaging stops, defining a tissue receiving area; and the '544 patent covers the clamp at the end of the outer tube and the mechanism that pivots the clamp. *See Tyco Healthcare Group, LP v. Ethicon Endo–Surgery, Inc.* (*Tyco II*), 411 F. Supp. 2d 93 (D. Conn. 2006).

ultimately found equivalence does not diminish the difficulty of their task, which must be viewed objectively.") (internal quotation marks and citations omitted).

In the wake of *Seagate*'s heightened standard of non–negligent, objective recklessness, courts may be presented with more successful motions for summary judgment of non–willful infringement, *see, e.g.*, *Cordance Corp., v. Amazon.com, Inc.*, 639 F. Supp. 2d 406, 415 (D. Del. July 29, 2009) (granting summary judgment where plaintiff's argument that "[defendant's] focus on technology means that it 'should have known' of [plaintiff's] . . . patents suggests the negligence standard for willful infringement overruled by *Seagate*"), where courts could conclude that the need for "close factual inquiry" or the presence of "hotly contested" claim constructions preclude as a matter of law any finding of willfulness. However, the differentiation between issues that are "hotly contested," "close," and "require an intensely factual inquiry" so as to preclude a finding of willful infringement before trial, and trial evidence which typically involves hotly contested issues and intense factual inquiries, including credibility determinations and inferences drawn from total circumstances, is not to be made just by incantation of these terms.

Here, although the record of evidence provided by both parties reveals the need for a fact–intensive inquiry on reduction to practice of the LCS–5, the Court is unpersuaded that this hotly contested issue with substantial damages implications should be decided on summary judgment. Ultimately, Ethicon may be able to establish invalidity based on reducing the LCS–5 to practice before March 1997, or at least that it had a reasonable good faith basis for claiming its priority, entitling it to judgment as a matter of law. *See, e.g.*, *Arlington Industries, Inc. v. Bridgeport Fittings, Inc.*, 692 F. Supp.2d 487, 504 (M.D. Pa. 2010) (granting the defendant judgment as a matter of law on the willfulness claim and noting, "in

spite of the jury's verdict, the court cannot ignore the contrary claim construction" and "the *Markman* hearings were hotly contested"); *OPTi Inc v. Apple, Inc.*, No. 2:07cv21(CE), 2009 WL 4727912, *3 (E.D. Tex. Dec. 3, 2009) (although the jury ultimately rejected Apple's invalidity defense, the "issue was, viewed objectively, sufficiently close to preclude a finding of willful infringement"); *Centocor Ortho Biotech v. Abbott Laboratories*, No. 2:07cv139(TJW), slip op. at 6 (E.D.Tex. Oct. 1, 2009), *aff'd*, 636 F.3d 1341 (Fed. Cir. 2011) (finding that defendant "consistently articulated objectively legitimate and reasonable defenses, that if true, would invalidate the patent"); *Safoco v. Cameron International Corporation*, No. H–05–0739, 2009 WL 2424108, *22–23 (S.D. Tex. July 31, 2009) ("at least one of [defendant's] non–infringement arguments presents a close factual question for some of the accused infringing devices," finding that the dispute about when the rotation capability of the invention should be assessed created "the type of close factual question that precluded a finding of willful infringement in *Depuy*"). However, the record as it stands now presents substantial testimony that if credited shows that Ethicon's prototypes were unable to regularly or reliably cut and coagulate tissue and blood vessels to be encountered in human surgery. *See, e.g., Arlington Indus. v. Bridgeport Fittings*, No. 3:01cv485(CCC), 610 F. Supp. 2d 370, 389 (M.D. Pa. Feb. 4, 2009) ("Proper adjudication of the willful infringement issue requires the factfinder to examine the totality of the circumstances," and "much of this evidence [of recklessness] requires judgments of credibility," thus, "the ongoing conflict regarding the existence of infringement . . . compel resolution of this [willful infringement] question by the jury.").[7]

[7] After the case went to trial in *Arlington Industries, Inc. v. Bridgeport Fittings, Inc.*, 692 F. Supp.2d 487 (M.D. Pa. 2010), although the jury found for the plaintiff on the claim

B. Non–Infringement Defense

Ethicon notes that 24 of the 31 claims asserted by Tyco require "some aspect of a cam mechanism," and argues that because Ethicon's accused instruments lack a camming mechanism, Ethicon has put forth a non–infringement defense sufficient to warrant summary judgment on the willful infringement claim. (Def.'s Mem. at 22.) Ethicon cites trial testimony provided by Mr. Whipple, in which he described how UltraCision engineers specifically considered—and rejected—the idea of using a cam mechanism in favor of a "rack–and–pinion gear mechanism" in the prototype devices. (Trial Tr., Ex. 12 to Def.'s Mem. at 1374:21–1376:24; 1394:14–1395:17; 1397:7–1398:13.) Mr. Whipple showed the design documents created at the time the UltraCision was being developed, testifying, "[the drawing is] a gear and rack type. When this was developed, it was originally multiple tooth gear and multiple tooth rack. As we progressed into developing it, we found that we could get by with one tooth on each and obtain the motion that we needed on the clamp arm." (*Id.* at 1376:15–20.)

Though both parties agree that a cam mechanism is distinguishable from a rack–and–pinion mechanism (*see* Durfee Dep., Ex. 22 to Def.'s Mem. at 94:5–9), Ethicon presents its argument as if the functional distinction between a cam mechanism and rack–and–pinion mechanism is crystal clear. However, at oral argument, the parties were in disagreement about what type of mechanism, exactly, Ethicon was using in its prototypes. Attorney Wintringham, for Tyco, argued:

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of willful infringement, the court granted judgment as a matter of law to the defendant, noting that the claim construction was too "hotly contested" to meet the requirements of a finding of willfulness. *Id.* at 504.

> They say it's not a cam, it's a rack and pinion. Regardless of what you call it, and we don't believe it is a rack and pinion, but regardless of what you call it, it's what is taught in the patent. . . . You've got basically camming members sitting in slots where the slots are guiding the motion and imparting motion to those camming members. So, we think that there is also clearly a high likelihood of infringement of valid claims on the camming issue as well.

(July 25, 2011 Tr. at 34:5–13.) In response, Attorney Maslowski reiterated the position that Ethicon took at trial, and referenced a prototype design from 1997 that "specifically says that they are using a slot in the inner tube to act as a rack for a single tooth, and they point to the tooth which is going to mate with the rack on the clamp arm. So, again, it's a modified rack and pinion." (*Id.* at 72:19–25.) Mr. Maslowski further emphasized that "years before this litigation was filed, there is evidence showing that our engineers specifically considered using a cam and rejected the idea in favor of this rack and pinion design." (*Id.* at 73:3–7.)

Though Ethicon can show that a rack and pinion mechanism was contemplated in their prototype drawings, it has not shown with sufficient clarity that what is actually used in the accused products functions as a rack and pinion in a manner which is distinguishable from a cam mechanism. Thus, the Court finds that a full trial record is required before a determination can be made as to whether Ethicon's non–infringement defense is reasonable.

III. Conclusion

Accordingly, Defendant's [Doc. # 60] Motion for Partial Summary Judgment of No Willful Infringement is DENIED.

IT IS SO ORDERED.

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

Dated at New Haven, Connecticut this 23rd day of September, 2011.