14-1764, 14-1791

# United States Court of Appeals for the Federal Circuit

**KONINKLIJKE PHILIPS N.V., PHILIPS ELECTRONICS NORTH AMERICA CORPORATION**,

*Plaintiffs-Appellants*,

v.

**ZOLL MEDICAL CORPORATION,**

*Defendant-Cross-Appellant.*

Appeal from the United States District Court for the District of Massachusetts
Case No. 1:10-CV-11041-NMG, Judge Nathaniel M. Gorton

## PRINCIPAL AND RESPONSE BRIEF OF DEFENDANT AND CROSS-APPELLANT ZOLL MEDICAL CORPORATION

David I. Gindler
Alan J. Heinrich
David C. McPhie
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276
Telephone: (310) 277-1010
Facsimile: (310) 203-7199

*Attorneys for Appellee and Cross-Appellant*

February 9, 2015

# CERTIFICATE OF INTEREST

Counsel for Defendant-Appellee and Cross-Appellant ZOLL Medical Corporation certifies the following:

1. The full name of every party or amicus represented by me is:

ZOLL Medical Corporation

2. The name of the real party in interest represented by me is:

ZOLL Medical Corporation

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Asahi Kasei Holdings U.S., Inc.
Asahi Kasei Corporation

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

IRELL & MANELLA LLP
Morgan Chu
David I. Gindler
Alan J. Heinrich
David C. McPhie
Rebecca L. Carson
Talin Gordnia
Christopher Vanderlaan
C. Maclain Wells
Christine Woodin

COOLEY LLP
James P. Brogan
Christopher C. Campbell
Matthew J. Leary

SHERIN AND LODGEN LLP
Thomas F. Maffei
Sara Jane Shanahan

FISH & RICHARDSON, P.C.
Matthew C. Bernsten
Betty H. Chen
Kevin J. DeJong
Gauri M. Dhavan
John A. Dragseth
Kurt L. Glitzenstein
Tal Kedem
Adam J. Kessel
Proshanto Mukherji
Olivia T. Nguyen
Young Park
Jennifer N. Scarpati
Frank E. Scherkenbach
Brian K. Wells
Jenny A. Shmuel

Respectfully submitted,

Dated: February 9, 2015 */s/ David I. Gindler*

David I. Gindler
Alan J. Heinrich
David C. McPhie
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276

Counsel for Defendant-Appellee and Cross-Appellant ZOLL MEDICAL CORPORATION

# TABLE OF CONTENTS

**Page**

**Page**

**Page**

# TABLE OF AUTHORITIES

**Page(s)**

## Cases

**Page(s)**

**Page(s)**

**Page(s)**

**Page(s)**



**Statutes**



**Rules**

## STATEMENT OF RELATED CASES

In addition to the proceedings referenced in Philips's opening brief, ZOLL Medical Corporation ("ZOLL") notes the following:

On September 21, 2012, Philips asserted U.S. Patent Nos. 5,749,905 ("'905 patent"), 5,607,454 ("'454 patent") and 6,047,212 ("'212 patent") against ZOLL Lifecor Corporation in Case No. 2:12-cv-01369 pending in the Western District of Pennsylvania.

On October 14, 2014, ZOLL submitted an *ex parte* reexamination request against claim 43 of U.S. Pat. No. 5,879,374 ("'374 patent"). *See* Control No. 90/013,373. On December 16, 2014, the United States Patent and Trademark Office ("USPTO") issued a decision finding multiple substantial new questions of patentability and initiating reexamination proceedings as requested.

On November 17, 2014, ZOLL submitted an *ex parte* reexamination request against claims 42, 67, and 68 of the '374 patent. *See* Control No. 90/013,401. On December 16, 2014, the USPTO issued a decision finding multiple substantial new questions of patentability and initiating reexamination proceedings as requested.

On January 8, 2015, ZOLL submitted an *ex parte* reexamination request against claim 7 of U.S. Patent No. 5,800,460 ("'460 patent"). *See* Control No. 90/013,424. On February 9, 2015, the USPTO issued a decision finding multiple

substantial new questions of patentability and initiating reexamination proceedings as requested.

## STATEMENT OF JURISDICTION

The District Court had jurisdiction under 28 U.S.C. § 1338(a) and entered final judgment of liability on June 20, 2014. On August 13, 2014, the District Court denied ZOLL's Fed. R. Civ. P. 50(b) motion. ZOLL filed a notice of appeal on August 23, 2014. This Court has jurisdiction under 28 U.S.C. §1292(c)(2).

## STATEMENT OF THE ISSUES

### ZOLL's Cross-Appeal (2014-1791)

1. Is ZOLL entitled to judgment of non-infringement of the '454 and '905 patents, which require monitoring an electrical parameter *during* the step of "discharging" an energy source, where (a) the District Court acknowledged that the patentee equated "discharging" with delivering a therapeutic "shock," but failed to instruct the jury on this meaning, and (b) it is undisputed that the accused devices monitor an electrical parameter during a test pulse *before* delivering a therapeutic shock?

2. Is ZOLL entitled to judgment of no direct infringement of the '454, '905, and '212 patents because Philips presented no evidence that ZOLL itself used the accused devices with an actual "patient," as required by every asserted claim of these patents?

3. Is ZOLL entitled to judgment of no direct infringement on all but one asserted claim of ’374 and ’460 patents because Philips failed to present evidence that ZOLL itself used the accused devices to perform each step of the self-test methods of these patents?

4. Is ZOLL entitled to judgment as a matter of law that all asserted claims of the ’374, ’460 and ’905 patents are invalid, where ZOLL put on a compelling case of invalidity and Philips offered no meaningful rebuttal?

**Philips’s Appeal (2014-1764)**

1. Should this Court take the extraordinary step of overturning the jury verdict of no contributory infringement and entering judgment against ZOLL, where the jury had ample evidence to conclude that (a) ZOLL did not have the required state of mind for contributory infringement, a quintessential jury issue, and (b) Philips did not prove the other elements of contributory infringement?

2. Should this Court overturn the jury verdict that the asserted claims of the ’526 patent are not indefinite, where the jury reasonably resolved a factual dispute between the parties’ experts?

3. Did the District Court abuse its discretion by determining that Philips was not entitled to a new trial based on (a) jury instructions that fairly reflect the standard for indefiniteness considered as a whole, or (b) exclusion of documents for which Philips failed to provide an adequate foundation?

## STATEMENT OF THE CASE

### I. The Parties

Dr. Paul Zoll was a pioneer in defibrillation and cardiac pacing, and the first person to externally defibrillate a patient. A1928:7-29:2. Dr. Zoll co-founded ZOLL in 1980 to commercialize his inventions. A1926:25-27:11. In 1988, ZOLL introduced its first external defibrillator: the PD1200. A1930:8-19. Among many other features, the PD1200 and follow-on PD1400 performed self-tests to ensure that the devices were working properly. A1930:25-31:9; A1939:14-40:24; A2874:6-23; A19057.

Philips is the successor to the assets of Heartstream, Inc., founded in 1992 by individuals previously employed by long-time market leader Physio-Control. A2019:13-21; A17305; A2644:1-45:8. Beginning in 1993 and 1994, Heartstream filed several applications for patents that would later be asserted in this case. *E.g.*, A363; A378; A392; A421; A438. Heartstream was acquired by Hewlett Packard in 1998, which then spun off Heartstream's assets into Agilent Technologies in 1999. A2018:4-19:3. In 2001, Agilent sold its medical division, including the patents-in-suit, to Philips. *Id.*

### II. Background On Philips's Technology

Shortly after Heartstream's launch, Physio-Control sued Heartstream and its founders—including four named inventors of the patents-in-suit—for

misappropriation of trade secrets. A2019:13-21; A16741. These alleged trade secrets encompassed many of the technologies claimed in the patents now asserted against ZOLL. *Id.* Heartstream and the four named inventors argued in their defense that these features were already "known and readily ascertainable" by the public before their company's founding in 1992. A17302-05.

For example, the '905 and '454 patents claim a defibrillator that monitors and shapes an electrotherapeutic "waveform" of energy *during* its discharge to a patient. Yet in the Physio-Control lawsuit, Heartstream's inventors admitted that "it was known and readily ascertainable" before their company's founding in 1992 that "[a] selected biphasic waveform can be delivered to a patient by *monitoring an electrical parameter during the discharge of the defibrillation pulse* and using it to adjust the shape of the waveform." A17302-04 (citing references). In fact, the Kroll patent, U.S. Pat. No. 5,431,686, discloses just that: discharging energy to a patient and waiting to begin the reverse phase of the waveform until a particular voltage is reached (*i.e.*, monitoring and shaping during discharge). A17382.

Philips's '374 and '460 patents claim to improve upon "self-test" techniques used in external defibrillators, such as by automating periodic self-tests performed before use (instead of manually pushing a test button). Yet the Heartstream inventors admitted that it was known before 1992 that an external defibrillator "can contain a self-test system that automatically follows a built-in test protocol using a

self-test signal every 24 hours." A17304-05. Philips's patents also include a claim to a "fail-safe" display that can indicate self-testing results even after power failure. Such a display was likewise known in the prior art. For example, a prior art brochure for the VIVAlink defibrillator discloses a "visual warning" of failure that "remain[s] indefinitely" even after the "batteries are exhausted." A14942.

## III. Background On ZOLL's Technology

ZOLL has a rich history of innovation. In 1992, for example, ZOLL employees filed a patent application directed to defibrillator electrodes, which issued as U.S. Patent No. 5,330,526 ("'526 patent"). A343. Industry consensus at the time taught that electrode impedance should be as low as possible to maximize transfer of energy to the patient. A346 at 1:46-56. The inventors of the '526 patent had the novel insight that using electrodes with impedance greater than 1Ω permits effective defibrillation while minimizing burns on patients' skin. *Id.*at 2:15-44. Another example is ZOLL's U.S. Patent No. 5,391,187, which claims a novel, life-saving defibrillator heart alarm. A352. The jury found that Philips infringed both of these patents, but Philips has only appealed the judgment as to the '526 patent.

ZOLL also developed its own unique defibrillator waveform ("rectilinear biphasic") and obtained six patents on that innovation. A1949:14-50:19. ZOLL's waveform is described in its patents, such as U.S. Patent No. 5,733,310 ("'310 patent"), and was the subject of extensive trial testimony, including from one of its

named inventors, Michael Lopin. A14774. Mr. Lopin used Figure 1 of the '310 patent (reproduced below) to explain the waveform used in ZOLL's accused products. A14776; A14789 at 4:16-35; A2390:5-91:17; A2397:9-2401:1.

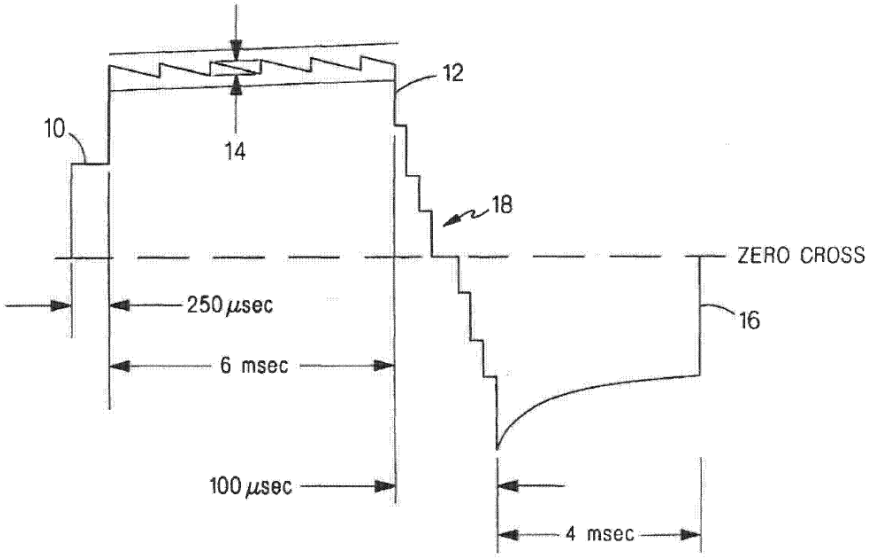



FIG.1

ZOLL's defibrillation method begins "with an initial 'sensing pulse' **10**, which has *insufficient energy for performing therapy*." A14789 at 4:16-35. The sensing pulse is "immediately followed by a biphasic defibrillation waveform having sufficient energy for defibrillating the patient's heart." *Id.* In most cases, ZOLL's waveform "includes a six-millisecond, generally rectilinear positive phase **12** having sawtooth ripple **14**, which in turn is followed by a four millisecond negative phase **16**…." *Id.*

The patient's impedance is measured during the non-therapeutic test (or "sensing") pulse prior to the delivery of the defibrillating shock to the patient.

A1733:22-34:1. That impedance information is used to select an initial value of resistance in the circuit and a time sequence for how individual resistors in a digital to analog converter ("DAC") will be shorted out during the electrotherapeutic shock to maintain a flat and fixed current. A2397:15-98:4. The sequence for shorting out the resistors is referred to as the "schedule" for the waveform. *Id.* The impedance is thus measured, and the schedule is selected, *before* the therapeutic shock is delivered to the patient. A2397:15-8:14.

ZOLL's unique rectilinear biphasic waveform, which it began using in 1999 in its M Series defibrillator, is the only biphasic waveform cleared by the FDA as clinically superior to monophasic waveforms for certain indications. A1953:3-14. Philips cannot claim clinical superiority to monophasic waveforms. *Id.*

## IV. Philips's Long Delay In Bringing Suit Against ZOLL

Philips contends that ZOLL's infringement began in 1999 with the M Series, which Philips did not accuse of infringement until 2012. *Compare* A5801 ¶17 with A5777 ¶17. However, the long history of the parties' interactions reflects that neither ZOLL nor (for many years) Philips itself believed that ZOLL was infringing, despite ZOLL's public announcements regarding its technology. Indeed, Philips waited until 2008 to even approach ZOLL about its patents. A1978:16-25. Philips presented ZOLL with a "stack" of more than 100 patents and told ZOLL that it needed to take a license because the patents were so numerous

that ZOLL's automatic external defibrillators—its AED Plus and AED Pro—"must be violating some of them." A1979:1-6; A2022:11-12. Philips later identified "ten patents" it claimed were infringed by ZOLL's AEDs. ZOLL responded that it did not need a license because, based on its analyses, Philips's patents either were not infringed or invalid. A12706-13; A1981:9.

In June 2010, Philips filed this suit, asserting fifteen patents against ZOLL's AEDs. The complaint asserted new patents that were not among the ten Philips previously identified, including the '454 and '905 patents. *Id.*; A5753-55 ¶¶1, 16; A5; A191. ZOLL responded with claims of patent infringement against Philips. Nearly two years later, Philips amended its complaint to accuse ZOLL's E Series, M Series, R Series, and X Series hospital defibrillators. A5801 ¶17. By trial, Philips had dropped more than half of its patents from the lawsuit. A104-111.

A ten-day jury trial followed. A132. The jury found that Philips directly infringed two ZOLL patents and that ZOLL directly infringed five Philips patents. A105-A116. The jury also found that ZOLL did not infringe any claims of two Philips patents and claims 66 and 73 of Philips's '374 patent. A105-A111. Further, the jury found that ZOLL's E Series and M Series defibrillators did not infringe any claims of Philips's '374 and '460 patents. *Id.* Philips has not appealed these findings. Finally, the jury rejected Philips's claims of contributory and induced infringement. A105-110. Philips has not appealed the jury's finding of no induced

infringement, pursuing only an appeal of the jury's finding of no contributory infringement. Br. at 2-3.

On the remaining claims, ZOLL filed a detailed motion for judgment of invalidity and non-infringement under Fed. R. Civ. P. 50(b), but the District Court denied the motion without explanation, simply inscribing on the first page of ZOLL's motion, "Motion denied." A9.

## SUMMARY OF ARGUMENT

In its claim construction order, the District Court acknowledged that the "discharging step" of the '454 and '905 patents was "not intended to describe every possible delivery of energy" and that the patentee equated this step with delivering a "shock" to a patient. A82. Nevertheless, the District Court failed to properly construe this term in accordance with these findings, A137:17-20, thereby relegating a dispositive claim construction dispute on these patents to the jury. The undisputed facts show that, under the correct construction, ZOLL does not infringe these patents.

The intrinsic record confirms that "discharging" means delivering a therapeutic shock to the patient and that Philips's patents require measuring an electrical parameter *during* the administration of that shock—not during a non-therapeutic test pulse. Indeed, the '454 patent distinguishes prior art that performs its monitoring during a "test pulse" that occurs "*prior to* administering the

defibrillating shock." A371 at 3:9-19. It is undisputed that ZOLL's defibrillators measure impedance during a non-therapeutic test pulse prior to administering the electrical discharge that actually defibrillates the patient. A1733:22-34:1. ZOLL is thus entitled to judgment of non-infringement of the '905 and '454 patents.

The District Court also erred in denying ZOLL's JMOL motion for nine of the ten Philips claims found *directly* infringed. (The tenth claim is the invalid "fail-safe visual display" claim, '374, cl. 43.) The three asserted method claims of the '454 and '905 patents include the step of "deliver[ing] electrical energy to [a] *patient*." A391; A376. Similarly, the asserted system claims of the '212 patent require electrodes in "electrical communication with the exterior of a *patient*." A451. Philips failed to offer any evidence that ZOLL used the accused devices to practice the "patient" limitations of these claims—because ZOLL is not a care provider and does not treat patients. Philips also failed to offer evidence that ZOLL itself performed every step of the self-test method claims ('374, cl. 42, 67, 68; '460, cl. 7), including performing self-tests "periodically" (rather than just once during internal pre-sale testing) and "automatically" (rather than initiated by a ZOLL technician). Judgment of no direct infringement should be entered for those claims.

ZOLL also presented unrebutted evidence demonstrating the invalidity of the asserted claims of the '374 and '460 patents. Philips did not even attempt any

analysis of the VIVAlink brochure's disclosure of a "fail-safe visual display" that would "remain indefinitely" even after the "batteries are exhausted," or of the Wiley patent's (U.S. Patent No. 5,579,234) disclosure of some self-tests performed "every hour" and other self-tests performed at a particular time each day. Nor did Philips dispute that technologies for computerized automation were available and readily applicable to automate defibrillator self-tests that were already known in the prior art, including ZOLL's own PD1400 product.

ZOLL's anticipation case for the '905 patent went unrebutted as well. ZOLL demonstrated that the Kroll patent discloses monitoring an electrical parameter (voltage) during delivery of a shock to a patient, which is used to determine how long the first phase will run before initiating the second waveform phase. Philips's only response was to argue that Kroll does not disclose a phantom limitation found nowhere in the '905 patent claims.

Turning to Philips's appeal, Philips asks this Court to take the extraordinary step of overturning the jury's verdict of no contributory infringement and entering judgment against ZOLL. Philips cites no case in which this Court ever granted such relief, and for good reason. Contributory infringement requires proof that the accused infringer *knew* that its activity would cause infringement by others, and state of mind is a quintessential jury issue. On this fact-intensive issue, a reasonable jury could easily conclude that Philips failed to meet its burden of

proving ZOLL had the requisite state of mind. The trial record likewise provided ample basis for the jury to conclude Philips failed to establish other elements of contributory infringement, such as predicate acts of infringement by others and the absence of substantial non-infringing uses for the accused products.

The Court should similarly reject Philips's attempt to disturb the jury's verdict that the asserted claims of ZOLL's '526 patent are not invalid as indefinite. This issue involved a factual dispute between the parties' respective experts, and the jury was entitled to reject the testimony of Philips's expert, who admittedly did not perform the claimed bench test according to the parameters specified in the claims.

Finally, Philips has failed to present any basis for a new trial on the '526 patent. The Supreme Court's *Nautilus* decision presents no fatal conflict with the District Court's multi-part instructions on indefiniteness, in light of the overall instructions. The District Court also did not abuse its discretion in excluding documents for which Philips failed to provide an adequate foundation.

## STANDARD OF REVIEW

The District Court's claim construction is reviewed *de novo* because it did not rely on any underlying factfinding but instead reviewed only the intrinsic record. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

The District Court's denial of a JMOL motion is reviewed *de novo*. *Marcano Rivera v. Turabo Med. Ctr. P'ship*, 415 F.3d 162, 167 (1st Cir. 2005). Because Philips had the burden of proving infringement, Philips must have introduced "substantial evidence" in support of each element to overcome ZOLL's JMOL motion for non-infringement. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1157 (Fed. Cir. 1998). In contrast, Philips may only overturn the verdict of no contributory infringement if "the evidence points so strongly and overwhelmingly in favor of [contributory infringement] that no reasonable jury could have returned a verdict adverse to [Philips]." *Rivera*, 415 F.3d at 167.

With respect to obviousness, this Court "reviews a jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1324 (Fed. Cir. 2008).[*] With respect to indefiniteness, the jury's factual finding that a person of ordinary skill in the art ("POSITA") would understand what is claimed is reviewed for substantial evidence. *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1360 (Fed. Cir. 2009).

[*] Internal citations and quotations are omitted and emphases are added unless otherwise noted.

To obtain a new trial due to jury instructions, Philips must establish that the instructions were legally erroneous and had prejudicial effect. *Sulzer Textile A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004). Under First Circuit law, this Court "review[s] for abuse of discretion questions as to whether the court's choice of phraseology in crafting its jury instructions is unfairly prejudicial." *Decaro v. Hasbro, Inc.*, 580 F.3d 55, 61 (1st Cir. 2009). Evidentiary rulings are also reviewed for an abuse of discretion. *Gen. Electric Co. v. Joiner*, 522 U.S. 136, 141 (1997).

## ARGUMENT ON ZOLL'S CROSS-APPEAL

### I. ZOLL's Defibrillators Cannot Be Used to Practice the '905 And '454 Patents

Claims 4 and 8 of the '905 patent and claim 51 of the '454 patent ("waveform method claims") recite methods for "delivering [or applying] electrotherapy" that include the steps of (1) "discharging the energy source … to deliver electrical energy to the patient in a [multiphasic] waveform" and (2) "monitoring an electrical parameter during the discharging step." A391; A376. ZOLL proposed to construe the term "discharging step" as "the electrotherapeutic shock, not a test pulse to measure patient impedance." A5835. The District Court committed legal error when it failed to properly instruct the jury that the "discharging step" refers to delivering an electrotherapeutic shock. Under the correct construction, ZOLL cannot be found to infringe these claims because the accused devices do not monitor an electrical parameter during the delivery of an

electrotherapeutic shock. At minimum, ZOLL is entitled to a new trial under the correct construction.

### A. The "Discharging Step" Means Delivering An Electrotherapeutic Shock

In its claim construction order, the District Court recognized that the "'discharge step' was not intended to describe every possible delivery of energy from the energy source." A82. The District Court also acknowledged that the "patentee equated 'discharge' with 'shock'" in the intrinsic record. *Id.* Nevertheless, the District Court provided the jury with a non-construction: "the term 'the discharge step' means the step of discharging the energy source." A5311:19-20. ZOLL duly objected. A168:18-23. Through this non-construction, the District Court erroneously relegated a claim construction dispute to the jury. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it.").

The District Court should have construed the "discharging step" to mean delivering an "electrotherapeutic shock." The preambles of the waveform method claims specify that they are directed to "method[s] for *delivering electrotherapy* to a patient through electrodes connected to an energy source." A391 cl. 4, 8; A376 cl. 51. As the District Court correctly found, the preambles are limiting. A5310:19-21. Delivering electrotherapy is the whole purpose of the alleged invention. *See*

*Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed. Cir. 2008) (preamble limiting where it recited a "necessary and defining aspect of the invention"). Indeed, the patents summarize their "invention" as delivering "*electrotherapeutic* pulses for defibrillation and cardioversion." A388 at 2:37-38; A371 at 3:39-41. This description of the invention must be given meaning. *Genzyme Corp. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1099 (Fed. Cir. 2003).

The claim language directly links the "discharging" step with the delivery of "electrotherapy" recited in the preamble. The discharging step recites "discharging *the energy source* across *the electrodes* to deliver electrical energy to the patient *in a [multiphasic] waveform*." Thus, the same "energy source" and "electrodes" used to deliver "electrotherapy" as stated in the preamble are used to deliver "electrical energy to the patient" in the "discharging" step. The "electrical energy" delivered in the "discharging" step is thus the electrotherapeutic shock itself. This also means that a non-electrotherapeutic test pulse does not satisfy the "discharging" step.

The patents confirm that a non-electrotherapeutic pre-shock test pulse is not encompassed by the "discharging" step. They distinguish prior art methods that use "test pulses" from their invention. The prior-art test pulses were administered before "the defibrillation shock" to measure patient impedance—as with ZOLL's

test pulse. A371 at 3:9-19. For example, the '454 patent distinguishes the prior art Kerber reference as follows:

> The authors describe an external defibrillator that administers a test pulse to the patient *prior to administering the defibrillation shock*. The test pulse is used to measure patient impedance; the defibrillator adjusts the amount of energy delivered by the shock in response to the measured patient impedance.

A371 at 3:13-18. The specifications also distinguish prior art that similarly measured patient impedance prior to delivering the defibrillation shock, noting that "prior art defibrillators measure the patient impedance…and alter the shape of a *subsequent defibrillation shock* based on the earlier measurements." A370-71 at 2:66-3:2; *see also* A388 at 1:48-2:38. In contrast to monitoring impedance *before* administering the defibrillation shock, such as through use of a test pulse, the '454 and '905 patents describe and claim monitoring impedance *during the electrotherapeutic shock itself*. A370-71 at 1:15-18, 3:36-40; A388 at 2:34-52. *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (construing "body" as "one-piece structure" where patent distinguished invention from prior art comprised of multiple pieces).

The specifications further confirm that "during the discharging step" means during the electrotherapeutic shock. For example, the '454 patent explains that the purpose of the invention is to "control the shape of the waveform delivered to the patient *in real time* (i.e., *during delivery of the waveform*)." A372 at 6:12-15.

Further, Figures 3-5 of the '905 patent describe what happens after a user connects the defibrillator to a patient to "apply an electrotherapeutic shock to the patient." A390 at 5:1-6. After the first phase of the shock is initiated at Voltage A, "[d]ischarge of the first phase continues for at least a threshold time $t_{THRESH}$." *Id.* at 6-14. Voltage (an electrical parameter) is then measured to determine whether it has dropped below "voltage threshold $V_{THRESH}$." *Id.* at 14-22. If yes, "[d]ischarge then ends to complete the first phase." *Id.* at 22-26. If not, discharge continues until $V_{THRESH}$ is detected. *Id.* & FIGS. 4-5. Significantly, monitoring occurs during the electrotherapeutic shock—which the specification equates with the term "discharge." A1733:22-34:1. The patents never suggest the alleged invention encompasses monitoring an electrical parameter *before* delivering the electrotherapeutic shock. Rather, they equate that technique with the prior art.

During prosecution, the patentee further confirmed that the claimed invention requires monitoring during the therapeutic shock. For example, the patentee distinguished a prior art patent to Bell that permitted a user to select an energy dose before a shock:

> Since it delivers a quantity of energy determined by a selection made by the operat[or] *prior* to delivery of the shock, the Bell device does not adjust energy delivered to the patient based on a value of an electrical parameter monitored *during* discharge, as required by claim 35.

A9186 (emphasis in original). Thus, the patentee again equated the term "discharge" with "shock," and distinguished its claimed invention as monitoring an electrical parameter *during* the shock. Any construction of Philips's patent that extends the "discharging" step to encompass a schedule selection that precedes the shock would impermissibly recapture disclaimed subject matter. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The District Court should have instructed the jury that the "discharging step" means delivering an "electrotherapeutic shock."

### B. ZOLL's Products Do Not Monitor Impedance During the Shock

ZOLL does not infringe because its products do not monitor impedance during the "discharging step," properly construed. Instead, they measure patient impedance and select a schedule for the waveform *before* delivering the electrotherapeutic shock.

Philips's expert confirmed that "Zoll's products in this case **[1]** determine impedance during a sensing pulse, **[2]** use[] that to pick a schedule, and **[3]** it is that schedule that is then used to deliver the rectilinear biphasic defibrillation waveform." A1733:22-34:1. Thus, the test pulse through which impedance is measured *precedes* delivery of the electrotherapeutic shock. *See* A2397:15-99:23 (test pulse used to select therapy pulse); A1730-31:7 (therapeutic discharge portion comes after test pulse in ZOLL products); *see also* A1726:3-5; A2390:5-91:17;

A2397:9-2401:1; A2430:6-31:24. Philips's expert further agreed that "the [ZOLL] sensing pulse is not sufficient under any scenario to defibrillate a patient" and that it "does not have enough energy to defibrillate" a patient. A1731:19-32:8; A2431:4-24. Because ZOLL's products do not monitor an electrical parameter during delivery of the electrotherapeutic shock, ZOLL is entitled to judgment of non-infringement under the correct claim construction.

Philips took full advantage of the District Court's non-construction, inviting the jury during closing argument to recapture for Philips the very subject matter from the prior art that the patentee had distinguished: "You can call it a test pulse. You can call it whatever you want. …And you can't just simply take part of it and say this is therapeutic." A5254:6-12. Philips's entire infringement case turned on persuading the jury that the "discharge" step encompassed the non-electrotherapeutic release of energy in ZOLL's test pulse.

In light of the District Court's erroneous claim construction and the undisputed facts regarding the operation of the accused devices, the Court should enter judgment of non-infringement for ZOLL. At the very least, the Court should vacate the judgment and remand for a new trial under the correct claim construction because ZOLL demonstrated that its test pulse is not part of the therapeutic shock and jurors were unable to properly evaluate the importance of this evidence. *See Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1381 (Fed.

Cir. 2005) (erroneous claim construction affecting jury's verdict is ground for new trial).

## II. Philips Failed To Prove ZOLL Directly Infringed

Philips failed to present substantial evidence that ZOLL directly infringed the following claims: '454 patent, claim 51; '905 patent, claims 4, 8; '212 patent, claims 1, 5; '460 patent, claim 7; and '374 patent, claims 42, 67, 68. These are all method claims except the '212 claims, which are system claims.

The Supreme Court recently confirmed the requirements for direct infringement. To prove ZOLL directly infringed a method claim, Philips needed to present substantial evidence that ZOLL itself performed *all* steps of the claim. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014) ("[U]nder this Court's case law, the patent is not infringed unless all the steps are carried out."). To prove ZOLL directly infringed a system claim, Philips needed to present substantial evidence demonstrating that ZOLL made, used, sold, offered to sell, or imported a system having *all* elements of the claim. *See* 35 U.S.C. § 271(a); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 340 (1961) (*Aro I*) (manufacture and sale of "unpatented part of a combination patent" is not "direct infringement"). Philips failed to present substantial evidence of direct infringement by ZOLL.

### A. Manufacture And Sale Of A Product Capable Of Performing A Method Are Not Acts Of Direct Infringement

ZOLL's manufacture and sales cannot support a finding of direct infringement for Philips's asserted method claims as a matter of law. "The sale or manufacture of equipment to perform a claimed method is not direct infringement within the meaning of 35 U.S.C. § 271(a)." *Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003). Instead, "[m]ethod claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).

Philips directly contradicted this settled principle of law in opposing ZOLL's JMOL motion. Philips argued that "Zoll directly infringed by making and selling defibrillators that perform every step of the '454 and '905 method claims." A5893. Philips purported to rely on *SiRF Technology, Inc. v. ITC*, 601 F.3d 1319 (Fed. Cir. 2010), and *Ericsson, Inc. v. D-Link Systems, Inc.*, No. 6:10-cv-473, 2013 WL 4046225 (E.D. Tex. Aug. 6, 2013). But those cases did not overturn settled precedent, as this Court recently confirmed on appeal in *Ericsson* itself: "Contrary to Ericsson's assertions, our decision in *SiRF* did not create direct infringement liability whenever an alleged infringer sells a product that is capable of executing the infringing method." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1221 (Fed. Cir. 2014).

In *SiRF*, the accused instrumentality was not a product, but rather an "end-to-end *service*" called "InstantFix" provided by a GPS provider. *SiRF*, 601 F.3d at 1324. The Court affirmed a finding that this company directly infringed a method claim where the InstantFix service performed all steps of the claimed method, including steps performed by a satellite controlled by the company itself along with other steps performed by products in communication with that satellite. *SiRF*, 601 F.3d at 1324, 1330; *see also Ericsson*, 773 F.3d at 1219-22. In *Ericsson*, this Court made clear that *SiRF* did not apply where "all of the steps" were performed on a product "controlled by a third party." *Ericsson*, 773 F.3d at 1221-22. Accordingly, the Court reaffirmed that "none of our decisions have found direct infringement of a method claim by sales of an end user product which performs the entire method, and we decline to do so here[.]" *Id.* at 1222.

### B. Philips Failed To Prove ZOLL Directly Infringed The Waveform Method Claims

The waveform method claims include the step of "discharging the energy source across the electrodes to deliver electrical energy *to a patient*." A391; A376. These methods require actual therapeutic use of a defibrillator on a patient; there is no infringement unless an operator discharges an energy source to a patient. Yet Philips never presented any evidence that ZOLL itself performed this "discharging" step on an actual patient. Indeed, Philips's expert admitted on direct examination that ZOLL's testing did not satisfy this requirement:

> Q. What about Zoll itself?
>
> A. Zoll itself used the device probably in testing….
>
> *Q. There's no <u>patient</u> when the devices are tested, though, is there?*
>
> *A. Probably not*….

A1687:12-22.

ZOLL is in the business of making and selling defibrillators; ZOLL itself does not defibrillate patients. *Id.*; *see also* A2424:3-10. Without evidence that ZOLL tests defibrillators on patients, ZOLL's testing cannot establish direct infringement. *See Mirror Worlds, L.L.C. v. Apple Inc.*, 692 F.3d 1351, 1359 (Fed. Cir. 2012) (affirming JMOL of non-infringement where plaintiff failed to show defendant's testing "performed all of the steps in the claimed methods").

Philips also pointed to FDA-related clinical trials of ZOLL's defibrillators to support direct infringement. But putting aside that clinical trials are shielded from liability under 35 U.S.C. § 271(e)(1), Philips made no showing that ZOLL controlled the independent physicians conducting such trials. A2424:3-10 ("Q. Did Zoll have any control over these doctors who were involved in the study? A. No."). Moreover, all of those trials concluded long before the six-year window of liability in this case under 35 U.S.C. § 286. *See* A2426:17-20 (test results in 1999); A14794-802 (same); A1952:3-53:14 (brochure from 2000); A2417:4-28:6 (1983

study); A18663-70 (same); A2484:12-14 (undated clinical testing performed by others on only "some" products).

Finally, *SiRF* provides no support for the jury's direct infringement finding, even under Philips's infringement theory. Unlike in *SiRF*, no steps are performed by equipment over which ZOLL itself maintains control. *SiRF*, 601 F.3d at 1324, 1330.

Because Philips failed to present substantial evidence that ZOLL itself performed all steps of the waveform method claims, ZOLL is entitled to judgment of no direct infringement of those claims. *See Finjan, Inc. v. Secure Computing Corp*., 626 F.3d 1197, 1205-06 (Fed. Cir. 2010) (reversing infringement judgment where defendant sold accused products but did not perform claimed method).

### C. Philips Failed To Prove ZOLL Directly Infringed The '212 System Claims

Philips presented no substantial evidence of any acts of direct infringement by ZOLL for claims 1 and 5 of the '212 patent. These system claims require electrodes in "electrical communication with the exterior of a *patient*." A451. As demonstrated above, ZOLL does not itself *use* defibrillators with electrodes in "electrical communication" with a "patient." Moreover, ZOLL's manufacture and sale of defibrillators cannot establish direct infringement of these claims because the defibrillators do not include electrodes in electrical communication with a patient when ZOLL makes and sells them.

Philips opposed ZOLL's JMOL motion with nothing more than a *non sequitur*. Philips argued that, because ZOLL's defibrillators "are used with electrodes," and because "[e]very time the device is operated, those electrodes are in 'electrical communication with the exterior of a patient," it follows that "the devices themselves are made and sold with 'first and second electrodes in electrical communication with the exterior of a patient.'" A5895. That makes no sense. ZOLL's defibrillators are connected to patients only *when used*, not when ZOLL makes and sells them. *See Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994-95 (Fed. Cir. 2009) (reversing judgment of infringement where claims required particular configuration and no evidence existed that defendant placed accused product in claimed configuration).

Philips failed to present substantial evidence that ZOLL makes, uses or sells defibrillators that include every element of the asserted '212 patent claims. *Aro I*, 365 U.S. at 340. ZOLL is thus entitled to judgment of no direct infringement. The District Court's denial (without explanation) of ZOLL's motion for JMOL of non-infringement of the '212 patent should be reversed.

### D. Philips Failed To Prove ZOLL Directly Infringed The Self-Test Method Claims

Philips failed to present substantial evidence that ZOLL itself actually performed every step of the "self-test" method claims ('374, claims 42, 67, and 68; '460, claim 7). Philips relies primarily on its assertion that ZOLL's expert Dr.

Henry Halperin "admitted that Zoll's defibrillators infringed the self-test patents." Br. at 21. But the question posed to Dr. Halperin makes no sense with respect to the self-test *method* claims, which can only be infringed through *use* of a product (as opposed to the product itself). Philips itself appears to have interpreted this testimony to mean that the accused products have "self-test *capability*." A5266:8-11. But again, mere capability is insufficient to show that ZOLL directly infringed each of the self-test method claims. Direct infringement of a method claim requires proof that the defendant performed every step of the claimed method. *See Limelight*, 134 S. Ct. at 2117.

Phillips never presented evidence that ZOLL itself actually used the accused devices to perform every step of each of the self-test method claims. Philips attempts to rely on testimony of ZOLL's Donald Boucher as evidence that ZOLL actually used the accused devices in an infringing manner. However, Mr. Boucher's testimony only provides generalities about ZOLL's testing. In deposition testimony (introduced during Philips's direct examination of its infringement expert), Mr. Boucher agreed that "before the [accused products were] sold to a customer, [ZOLL] did validation testing or verification testing using a defibrillation analyzer to make sure the features and functionalities were working properly." A1897:18-98:11. Nothing in this testimony shows that ZOLL's testing involved using the accused devices to practice every step of every self-test method

claim—or even any step of any self-test method claim. Indeed, during his trial testimony, Mr. Boucher testified only that ZOLL "do[es] *some testing* of the [accused] products … including the self-test functionality," but made clear that ZOLL does not test "every single little thing that's in the product." A2482:24-83:4.

In particular, Philips presented no evidence that ZOLL itself ever:

- Performed self-tests "automatically" as opposed to testing prompted by a technician (all self-test method claims);
- Performed more than one self-test in a "periodic" manner ('460, claim 7; '374, claims 67-68);
- Tested using a "first" and "second" "periodic schedule" ('460, claim 7);
- Generated test signals "within the … defibrillator" as opposed to using external test equipment like a "defibrillation analyzer" (all self-test method claims);
- Conducted tests "prior to any attempted use of the defibrillator" ('374, claims 42, 67);
- Did testing "without human intervention" ('374, claim 67).

While Philips argues that the evidence shows "that Zoll configures its defibrillators to automatically run self-tests by default when shipped," any such evidence fails to show that ZOLL directly infringed any of the self-test method claims. This is because, as discussed above, the manufacture and sale of a product capable of performing a claimed method is not an act of direct infringement. *See Ericsson*, 773 F.3d at 1219-22. ZOLL is thus entitled to judgment of no direct infringement of the self-test method claims.

## III. ZOLL Established Invalidity Of The Asserted Claims Of The Self-Test Patents Without Meaningful Rebuttal By Philips

Judgment of invalidity should be entered as to the asserted claims of the self-test patents ('374, claims 42, 43, 67, 68; '460, claim 7). ZOLL presented a compelling case for invalidity of every claim, yet Philips chose to respond with nothing more than a few conclusory statements from its expert on validity. Philips cannot salvage the validity of these claims based on such empty "evidence."

Defibrillators with self-testing features were known in the prior art. Philips made this very point on direct examination of its own expert:

> Q. Okay. Doctor, just briefly on that point, to be fair … power on self-tests were known, right?
>
> A. Yes. …
>
> Q. And other types of self-tests were known, like battery insertion tests, right?
>
> A. That's right.
>
> Q. And pushing a button and the device would test itself, right?
>
> A. Yes.

A5097:7-19. Accordingly, the so-called "self-test" claims do not actually cover the broad concept of "self-testing" itself, but rather purport to add something to the known prior art on self-testing defibrillators:

- Claim 43 of the '374 patent adds a "fail-safe visual display."

- Claims 42, 67, and 68 of the ’374 patent add that self-testing be performed “automatically” and “periodically,” before the device is used.

- Claim 7 of the ’460 patent adds that such self-tests be performed on at least two periodic schedules.

ZOLL clearly demonstrated at trial—without meaningful rebuttal—that defibrillators incorporating these trivial self-testing variants were disclosed by and/or obvious over prior art.

### A. Claim 43 Of The ’374 patent Is Anticipated By The VIVAlink Brochure

Claim 43, known as the “fail-safe visual display” claim, reads in its entirety as follows:

> An external defibrillator comprising:
>
> [**a**] a high-voltage delivery system; and
>
> [**b**] a self-test system, the self-test system comprising a [**c**] test signal generator and a [**d**] fail-safe visual display.

A436. Philips’s expert illustrated the meaning of the claimed “fail-safe visual display” technology by pointing to a defibrillator that would display a “red X” to indicate that “there’s a problem” even if the device were “completely broken” or if “there’s no power applied.” A1325:5-25.

To prove anticipation, ZOLL relied on the VIVAlink product brochure (“VIVAlink”). A14941-44. VIVAlink describes an “Automatic External Defibrillator System” made by Survivalink, an early competitor to Heartstream.

*Id.*; A2034:3-10. VIVAlink is prior art to claim 43. *See* A2869:20-70:15; A5085:9-19; A5086:21-87:7; A5127:11-23. VIVAlink includes a passage that clearly discloses claim 43:

> While the VivaLink AED is dormant, the microprocessor will automatically check the conditions of the battery, the electrodes/electrode cables and the internal electronics every 24 hours. On a weekly basis, it will automatically check the capacitor, the charging circuit, and the high voltage circuit. *If any system is not within preset specifications*, an audible and *visual warning (Maintenance Alert) is triggered.* Audible warnings will last until the batteries are exhausted but the *visual signal will remain indefinitely.*

A14942.

ZOLL's expert Dr. Halperin explained how VIVAlink discloses every element of claim 43. A2842-43; A2848-50; A2864-65. For example, he pointed to VIVAlink's disclosure of an external defibrillator with a "high-voltage circuit" [element **43a**]. He emphasized VIVAlink's "*self-diagnostic* procedures" [element **43b**] that "automatically check the condition of the battery, … the charging circuit and the high-voltage circuit" using "*test signals*" [element **43c**] with a "microprocessor." *See, e.g.*, A2860:1-63:6 ("for the microprocessor to automatically check these things … a test signal has to be generated"); A14941-44. And for the claimed "visual display," Dr. Halperin cited VIVAlink's description of an "audible and *visual warning*" that would be presented if any system is "not within preset specifications." *See, e.g.*, A2861:10-17; A14942. Dr. Halperin found

that this visual display was "fail-safe" based on VIVAlink's disclosure that "*the visual signal will remain indefinitely" even after the "batteries are exhausted*" [element **43d**]. *See, e.g.*, A2864:4-65:13; A14942. He thus concluded that claim 43 was anticipated by VIVAlink. A2864:4-9; A2893:7-15.

Philips did not present any meaningful rebuttal. In fact, the sum total of Philips's response to ZOLL's anticipation case under VIVAlink was the following two questions and answers during the examination of its expert, Dr. Efimov:

> Q. Doctor, do you have Exhibit 1123, the VivaLink brochure in front of you? Is this the prior art reference that Zoll relies on to show that Philips's self-test patents are invalid?
>
> A. Yes. This is very, very short, you know, a few pages brochure. And the relevant part for this consideration is right here. This is the only information available. So this does not really disclose the entire self-test because it does not teach how to make or use self-test. It does not disclose fail-safe visual display. More importantly, it does not disclose turning on of the power systems in response to a test signal, which is a critical part of a self-test.
>
> Q. In other words, Doctor, it's missing many critical claim elements?
>
> A. That's right.

A5095:19-96:7.

Dr. Efimov's conclusory testimony does not amount to substantial evidence sufficient to support a finding of no anticipation. The "[m]ost important[]" point of his testimony—that VIVAlink "does not disclose turning on of the power systems

in response to a test signal"—relates to an irrelevant limitation from claim 1 of the '460 patent ("turning on a power system … in response to the test signal"), which is absent from claim 43. *Id.* Indeed, there are only two aspects of this testimony that arguably relate to claim 43 at all.

First, Dr. Efimov testified that VIVAlink "does not disclose fail-safe visual display." *Id.* He provided no support for this assertion. In particular, he identified no deficiency in VIVAlink's disclosure of a "visual warning" that "remain[s] indefinitely" even when the "batteries are exhausted" "[i]f any system is not within preset specifications." A14942. Conclusory expert testimony is insufficient to prevent judgment of invalidity. *Muniauction*, 532 F.3d at 1318 (reversing denial of JMOL motion on invalidity where patentee's expert failed to present competent analysis of prior art); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426-27 (2007) (patent invalid despite "conclusory" expert testimony to the contrary).

Second, Dr. Efimov testified that VIVAlink "does not teach how to make or use self-test." A5095:19-96:7. Dr. Efimov's conclusory statement does not explain how VIVAlink's prominent disclosure of "self-diagnostic procedures" could fail to satisfy the "self-test system" element of claim 43. This testimony cannot constitute substantial evidence of no anticipation. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1346-48 (Fed. Cir. 2009). Accordingly, ZOLL is entitled to judgment of anticipation of claim 43.

### B. Claim 7 Of The '460 Patent Is Anticipated By The Wiley Patent

ZOLL presented an equally compelling case that claim 7 of the '460 patent is anticipated by the Wiley patent, U.S. Patent No. 5,579,234. A14913-40; *see* A392-406. Claim 7 is set forth below in the context of the three (unasserted) claims from which it depends (1, 5, and 6):

> 1. A method of performing a self-test in an external defibrillator, the method comprising the following steps:
>
> [**a**] generating a test signal automatically;
>
> [**b**] turning on a power system within the external defibrillator in response to a test signal; and
>
> [**c**] performing a plurality of automatic self-tests within the external defibrillator for determining the status of the defibrillator.
>
> [**claim 5**]…wherein the performing step comprises performing said plurality of automatic self-tests within the external defibrillator on a schedule;
>
> [**claim 6**]…wherein the performing step comprises performing a first automatic self-test on a first periodic schedule;
>
> [**claim 7**]…wherein the performing step comprises performing a second automatic self-test on a second periodic schedule.

Claim 7 was distinguished from the other asserted self-test claims in requiring a "second automatic self-test on a second periodic schedule." A5095:6-15. ZOLL proved at trial, without meaningful rebuttal from Philips, that adding a

second periodic test to a system that already had one periodic test was not novel as of the priority date of claim 7.

ZOLL's expert Dr. Halperin explained in detail how claim 7 was anticipated by the Wiley patent. *See, e.g.*, A2856:17-59:25. Dr. Halperin showed how the Wiley patent "indicates that the CPU test is done every hour on wake-up, and that the full suite of tests are done every 24 hours." A2856:3-6. He explained that the hourly "wake-up" is performed by "a real-time clock that generates a signal" [element **1a**]. This "wake-up" signal is generated "every hour" and triggers a "COLD START" signal that "power[s] up the CPU" [element **1b**]. A14931 at 6:15-20.

Figure 4A of the Wiley patent illustrates how the hourly and daily self-tests are performed at this point. A14918. The first step performed in response to the hourly wake-up signal is to conduct a CPU self-test (element 210). *Id.* The logic flow then arrives at element 224, where the current time is compared against the "Auto Test Start" time. *Id.* This condition will be true exactly once per day (e.g., "4:00 a.m."), in which case a more extensive battery of self-tests is performed. A14918-26; *see also* A2852:7-12 ("if that particular hour corresponds to an hour when the test is supposed to be run…then it runs the [more extensive] test[s]"); A2856:1-6; A2853:13-17; A2855:8-14. Thus, the Wiley patent discloses a "plurality of tests" as claimed in the '460 patent [element **1c**] on a schedule

[**claim 5**]. And as Dr. Halperin testified, the self-tests that run *every day* at a specific time (e.g., "4:00 a.m.") disclose a first periodic schedule [**claim 6**] (A2859:6-22; A14931), and the CPU's "standard power-up self-test" that occurs "every hour" discloses a second periodic schedule [**claim 7**]. *Id.* Thus, the Wiley patent discloses each element of the claim.

Dr. Efimov's testimony about the Wiley patent relating to the '460 patent was terse and uninformative:

> Q….[C]an we also just discuss [Wiley] with respect to what it doesn't show?
>
> A. It does not show at all the second periodic self-test on the second periodic schedule.
>
> Q. Is that because it only has a single periodic schedule?
>
> A. That's right. There's only one schedule 24 hours and multiple tests conducted on this one schedule.

A5095:6-15. Dr. Efimov did not refer to the actual text of the Wiley patent to explain how its CPU self-testing performed "every hour," along with other tests run at "4:00 a.m." daily, might not satisfy the "second periodic schedule" of claim 7. In short, this unsupported testimony simply cannot constitute substantial evidence of no anticipation by the Wiley patent. *Ecolab*, 569 F.3d at 1346-48.

### C. Claims 42, 67 and 68 Of The '374 Patent Are Obvious

ZOLL proved at trial that claims 42, 67, and 68 of the '374 patent were obvious based on existing self-testing defibrillators, including ZOLL's PD1400,

when considered in light of simple, well-known technologies for automating manual activities (such as the prior-art "real-time clock" circuit). This Court has repeatedly instructed that, even when submitted to the jury, obviousness "is ultimately a question of law decidable by the court in response to a motion for [JMOL]." *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 764 (Fed. Cir. 1988). Here, the District Court issued no written decision on this question of law when ruling on ZOLL's JMOL motion. A9 (merely noting "Motion denied").

As Philips itself noted, claim 42 consists of "three steps": (1) periodically generating a "test signal" (e.g., "once a day" or "once a month"); (2) initiating and performing a "self-test" in response to this signal; and (3) displaying the results of the self-test. A1831:17–32:12 (trial testimony of Philips's expert). Claims 67 and 68 are similar, introducing (respectively) the concept of a "plurality" of self-tests, and performing self-tests on a "predetermined schedule." A437.

The supposed point of novelty of these claims is that they are performed "automatically" and "prior to any attempted use of the defibrillator." A5097:20-22; A5131:7-11. Every other element of claims 42, 67, and 68 was well-known in the prior art. Dr. Halperin testified that ZOLL's PD1400 defibrillator and the Spacelabs First Medic 610 defibrillators (both available prior to 1993) automatically performed self-tests when turned on, and that this power-on self-test was a common defibrillator functionality prior to 1993. A2874:9-A2875:14;

A1939:14-40:24 (PD1400 sold in U.S. by 1992); A19057 ("The computer contained within the ZOLL PD1400 performs self-diagnostic tests on critical circuits when the instrument is initially turned on and periodically during operation."). Indeed, he testified that the specific self-tests in Philips's self-test patents were known in the prior art. A2875:11-14.

Philips did not dispute any of this; its own expert admitted that self-testing defibrillators were "known in the prior art," including "power on self-tests," "battery insertion [self]-tests," and the practice of "pushing [a] button" so that "the device would test itself." A5097:7-19. At trial, Philips repeatedly confirmed that the "automatic" nature of the self-testing distinguished the claims from the prior art. *See, e.g.*, A5096:16-18; A5097:20-22 ("what wasn't known [in the prior art] was the automatic test while the device sat on the shelf"). Philips's expert testified that this "automatic" aspect of the claims was the key alleged innovation over the prior art because it eliminated the "human interaction required for testing," which involved hospital staff manually "going and doing power-on self tests." A5101:15-A5102:5. According to Philips, the claims to "automatic and periodic self-tests" were "important" because they eliminated the need to have staff "push the button for tests." A1828:1-23.

Philips's attempt to rely on computerized automation to establish non-obviousness fails as a matter of law. "[I]t is well settled that it is not 'invention' to

broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result." *In re Venner*, 262 F.2d 91, 95 (C.C.P.A. 1958); *see also Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) ("Accommodating a prior art mechanical device that accomplishes [the same] goal to modern electronics would have been reasonably obvious to one of ordinary skill....").

Consistent with this long-standing precedent, ZOLL presented unrebutted evidence that the mere computerized automation of manual self-testing in a defibrillator would have been obvious. Specifically, ZOLL showed that timing circuitry for such automation was well-known before 1993 and trivial to incorporate into prior art self-testing defibrillators. A2873:23-2878:10. For example, ZOLL presented evidence of prior admissions from Heartstream that it was not a new idea to include in a defibrillator "a self-test system that automatically follows a built-in test protocol using a self-test signal *every 24-hours*." A17304. Heartstream based this view on "the work of several firms that were working in this field *in 1992*," including Spacelabs Medical's First Medic division and Survivalink Corporation's Vivalink AED division. *Id.* Moreover, Heartstream concluded that it had been known since at least 1984 to test battery conditions of medical devices "automatically once every four months by the expiration of a watchdog timer circuit." *Id.* (Imran patent, 1984). Indeed,

Heartstream stated that by 1992, "it was *generally known or readily ascertainable* that self-tests could be initiated by the defibrillator itself." A17305.

Dr. Halperin further testified that it would have been trivial before 1993 to modify prior art defibrillators (such as ZOLL's PD1400) with simple electronic timing components that would automate self-tests on a periodic basis. A2876:8-17. For example, Dr. Halperin testified regarding a component known as a "real-time clock," which was well-known at the time and existed for precisely the purpose of helping automate tasks to be performed on a regular, periodic basis. A2845:11-24; A2884:13-87:2; *see also* A17712-18031 at, *e.g.*, A17716-17. ZOLL's CEO Rick Packer similarly testified regarding "automated self-testing" technologies that existed "in the '80s," with systems that would "wake themselves up and check themselves." A1939-40.

Philips did not contradict any of this evidence. Philips's sole attempted critique consisted of a single question and answer from its expert:

> Q. And Doctor Halperin talked a lot about a real-time clock reference. Does that even talk about a defibrillator?
>
> A. No. It's just an electronics scan book.

A5097:23-25. Dr. Efimov never testified that automated timing circuits were not known prior to the critical date for these claims or that a POSITA did not know how to use them to automate tasks on a periodic basis. Instead, he addressed just

one of ZOLL's sources of evidence on this point and observed that it did not explicitly state that timing circuits should be implemented in defibrillators. But the Supreme Court has rejected the notion that a particular reference must provide explicit motivation to combine or modify in the face of evidence of a known, predictable solution. *See KSR*, 550 U.S. at 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). Indeed, the Supreme Court addressed this very issue:

> [I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

*Id.* at 417. Under *KSR*, Philips failed to rebut ZOLL's strong showing of obviousness.

### D. Secondary Considerations Do Not Save Philips's Self-Test Claims Due To Lack of Nexus

Philips failed to present evidence of secondary indicia of non-obviousness sufficient to save these claims. *See Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008) (reversing jury verdict of non-obviousness despite secondary considerations); *Leapfrog*, 485 F.3d at 1162-63 (Fed. Cir. 2007) (claim was obvious despite "substantial evidence" of secondary indicia of non-obviousness).

Philips conceded that that there was nothing unexpected about its automation of prior art self-test functionalities. A4012:1-3 (Philips conceding it lacked any evidence of "unexpected results"); A4012:7-8 ("I would agree that we don't have surprise or disbelief."). Philips instead attempted to rely on supposed evidence of commercial success, praise, or adoption by others, yet failed to meet its burden of establishing the requisite nexus to the specific elements of the asserted claims. *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (patentee bears burden of establishing "requisite nexus" to permit reliance on secondary considerations).

Philips's own evidence established that any purported success was merely attributable to marketing. For example, Ms. DiSanzo, Philips Healthcare's CEO, testified that Heartstream's Forerunner defibrillator "had no revenue at first," from head-to-head competition with Physio-Control's defibrillators. A2023:14-24. When asked why Hewlett Packard chose to purchase Heartstream, Ms. DiSanzo explained that focus groups indicated that people purchased the Forerunner because they "liked the look of the thing," because "it had a beautiful user interface," and because it was "very pretty." A2021:23-22:5 Ms. DiSanzo further testified that sales picked up because of Philips's marketing strategy of going "everywhere Physio Control isn't," such as airlines. A2024:9-25. This marketing strategy paid off when Philips received positive press about its AEDs in aircrafts.

A2027:17-28:16; A2028:16-19; A2029:1-2. Moreover, Ms. DiSanzo testified that Philips's subsequent sales of defibrillators were also driven by this early marketing success. A2029:14-30:11. Thus, Philips failed to offer competent evidence of secondary indicia to support the judgment of non-obviousness.

The only compelling evidence of secondary considerations presented at trial were facts showing "simultaneous invention"—a secondary consideration demonstrating *obviousness* (not non-obviousness). *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000). ZOLL demonstrated that there were a number of entities creating defibrillators with automatic self-test capabilities at least around the same time as Philips's purported invention. *See, e.g.*, A17304-05; A2876:18-87:23. For example, there was no dispute that VIVAlink and the Wiley patent disclosed automatic self-tests by July 1993 and March 1994, respectively. A2856:11-16; A5085:15-86:7; A5127:11-20; A2848:7-25; A2862:2-63:6; A5270:3-10. Philips claimed that its own automatic self-test claims predated this art, but even if true (which it is not), those claims only predated the Wiley patent and VIVAlink by a matter of months. *Id.*; *see also* A17304-05. This uncontradicted evidence of simultaneous invention weighs strongly in favor of obviousness.

## IV. ZOLL Established Invalidity Of The Asserted Method Claims Of The '905 Patent

ZOLL proved that claims 4 and 8 of the '905 patent were anticipated by the Kroll patent, U.S. Pat. No. 5,431,686. A17377-87. Philips's only response was that the Kroll patent did not disclose certain elements not actually recited in the claims. This is not a proper basis for a finding of no anticipation. *DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245, 1254 (Fed. Cir. 2014) (overturning verdict and finding claims anticipated where patentee improperly attempted to "introduce[] a limitation found neither in the [] patent's claims nor the parties' stipulated construction").

Claims 4 and 8 provide as follows:

> 4. A method for delivering electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:
>
> [**a**] discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;
>
> [**b**] monitoring a patient-dependent electrical parameter during the discharging step;
>
> [**c**] shaping the waveform so that an initial parameter of a waveform phase depends on a value of the electrical parameter.
>
> 8. The method of claim 4 wherein the initial parameter is current.

ZOLL's expert, Dr. Kroll himself, provided a detailed explanation of how his patent anticipates claims 4 and 8. A2645:3-49:22. Using as a guide Figures 2

and 7, reproduced below (red annotations added to Figure 2), Dr. Kroll mapped corresponding disclosures of his patent to each element of claim 4:

- The "Begin Delivering Energy From Capacitor" step of Kroll discloses the "discharging" step [**4a**].
- The "Wait Until Capacitor Discharge Voltage Decays Given Percentage" step of the Kroll patent discloses the "monitoring" step [**4b**]. The specification states: "Capacitor energy continues to be discharged until the capacitor discharge voltage decays a given percentage from the preselected amount of electrical energy stored in the capacitor (step 96)." A17387 at 9:52-55. As Dr. Kroll explained, discharging until the voltage decays to a preselected level necessarily involves monitoring the voltage to determine the moment when the preselected voltage level is reached. A2648; A5042, A5044 (Philips expert agreeing "voltage is monitored" in Kroll).
- For multiphase waveforms, the "Reverse Pulse Polarity" step discharges "what's left over from [the] positive phase for voltage," as shown in Figure 2 below. A2649. In other words, the decision regarding "when to stop the first phase" also "determin[es] the initial parameter of [the] next phase." *Id.* This was the exact theory that Philips used to argue infringement of claim 4. A1636 (arguing ZOLL

"determines what the first phase final amplitude would be, and so it also determines what the initial amplitude of the second phase will be and, thus, it shapes the waveform"); A5049:7-11. Thus, Kroll discloses the final "shaping" step **[4c]** as well.

*Fig. 7*

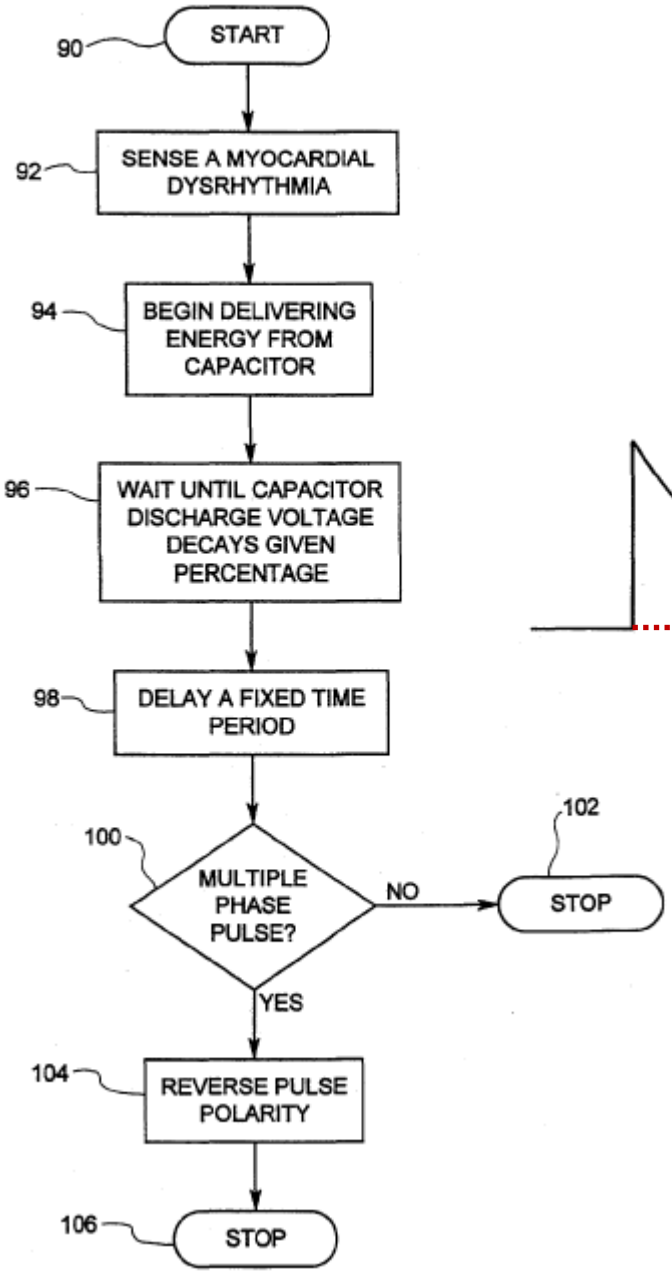
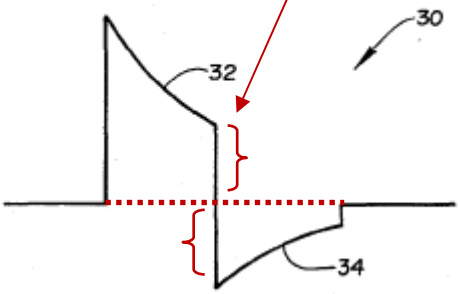



*Fig. 2*




capacitor discharged until first phase ending voltage

second phase initial voltage is same magnitude as first phase ending voltage (with reversed polarity)

Dr. Kroll also detailed how Heartstream had admitted the elements of claim 4 were known in the prior art—*even citing Dr. Kroll's own related work*. A2643:25-46:14; A2646; A17303.

Instead of disputing these points, Philips sought to import an extraneous "non-fixed" limitation into the shaping step [4c] and then argue that the Kroll patent did not disclose this phantom limitation. A5262:15-17 ("We don't have fixed parameters. We don't have fixed tilt."); A2711:11-16; A5262:7. But Philips never identified any textual basis in claim 4 for a negative limitation against "fixed" parameters. Just as in *DDR Holdings*, the verdict of no anticipation cannot stand based on a "limitation found neither in the [] patent's claims nor the [claim] construction." *DDR Holdings,* 773 F.3d at 1254.

With respect to the additional element of claim 8 ("initial parameter is current"), Dr. Kroll demonstrated that this was inherently disclosed in his patent, because determining an initial voltage also determines an initial current for any given value of resistance. A2649. This is because current and voltage are "proportional" to one another under well-known physical laws. *Id*.

Philips did not take issue with Dr. Kroll's application of this fundamental physical law. Instead, Philips sought to rely on conclusory expert testimony and another rewriting of the claim. First, Philips's expert made the irrelevant point that the Kroll patent did not explicitly discuss current as an initial parameter

(A5050:12-13), even though express disclosure is not required for inherency. Philips then argued that the Kroll patent did not invalidate claim 8 because it does not "use *monitoring* a current." A5262:22-23. But nothing in claim 8 requires *monitoring* current. Claim 8 only mentions current as an "*initial parameter*" that depends on the (generic) "electrical parameter" monitored during the discharge. Philips's validity argument is improperly premised on a phantom claim limitation. *Muniauction*, 532 F.3d at 1325 (reversing jury's verdict of validity where plaintiff's expert's testimony "was based on the absence of" a claim limitation "not required by the claims"). Accordingly, judgment of anticipation should be entered with respect to claim 8.

## ARGUMENT ON PHILIPS'S APPEAL

### I. Substantial Evidence Supports The Jury's Finding Of No Contributory Infringement

Philips requests that this Court grant the extraordinary relief of overturning a jury verdict of no contributory infringement and entering judgment of contributory infringement against ZOLL. Philips fails to cite a single case in which this Court granted such relief, and for good reason: Contributory infringement requires *knowledge* of infringement on the part of the accused infringer, and state of mind is an issue uniquely in the hands of the jury.

Because Philips challenges a jury verdict against it on an issue for which Philips bore the burden of proof, Philips faces an "especially exacting" standard to

overturn the verdict. *See Marrero v. Goya of P.R.*, 304 F.3d 7, 22 (1st Cir. 2002). Philips can meet this standard only if its evidence was "uncontradicted and unimpeached." *Id.* Thus, Philips's challenge must fail unless Philips established its case by "testimony that the jury is not at liberty to disbelieve." *Id.* (quoting *Jordan v. U.S. Lines, Inc.*, 738 F.2d 48, 49 (1st Cir. 1984). Philips cannot satisfy this standard.

### A. Philips Failed To Prove The Required Knowledge Of Infringement

To prevail on its allegations of contributory infringement of its method claims, Philips had to prove that ZOLL sold a material or apparatus "for use in practicing a patented process, constituting a material part of the invention, *knowing the same to be especially made or especially adapted for use in an infringement of such patent,* and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c). At a minimum, this means that "a violator of § 271(c) must *know* that the combination for which his component was especially designed was both patented and *infringing*." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 479, 488 (1964) (*Aro II*) (same).

In *Global-Tech*, the Supreme Court held that claims under § 271(b) and § 271(c) both require the "same knowledge" element: "knowledge that the [accused] acts constitute patent infringement." 131 S. Ct. at 2068. Even Philips

concedes that it cannot succeed on its claim for contributory infringement without proving that ZOLL *knew* that its activity would "cause infringement"—perhaps because the Federal Circuit has already corrected Philips at least once before on this issue. Br. at 40; *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330 (Fed. Cir. 2010) ("[W]e disagree with Philips' claim that it need only show that Netgear knew of the patent and of the relevant acts, not whether these acts *constituted infringement*.").

Notwithstanding this clear law, Philips now asks this Court to sit as a super-jury, reweigh the jury's credibility determinations regarding ZOLL's mental state, and overturn the verdict of no contributory infringement. This Court should reject Philips's invitation, as the weighing of evidence regarding a defendant's mental state is uniquely within the province of the jury. *Ericsson*, 773 F.3d at 1222 ("Questions of intent are quintessential jury questions."); *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 649 (Fed. Cir. 2011) ("[I]t is within the province of the jury to make credibility determinations" with respect to defendant's "state of mind and its bearing on indirect infringement."); *see also Farmer v. Brennan*, 511 U.S. 825, 842 (1994) ("Whether a [defendant] had the requisite knowledge … is a question of fact …."). Given this trial record, the jury had ample basis to disbelieve Philips's accusations that ZOLL knew it was causing actual infringement. *See Aro II*, 377 U.S. at 488.

### 1. Philips Relies On Inferences Least Favorable To The Verdict And Ignores The Jury's Resolution Of The Parties' Factual Disputes

Philips attempts to shift the burden for overturning the jury verdict to ZOLL by urging the Court to take all inferences in favor of Philips and *against the jury verdict*. Br. at 37-47. This is exactly backwards: a "reviewing court must view the evidence in the light most flattering to the verdict." S*ee Fresenius Medical Care Holdings, Inc. v. United States*, 763 F.3d 64, 67-68 (1st Cir. 2014).

For example, Philips contends that the jury was required to find the knowledge element satisfied because (1) a ZOLL patent prosecutor cited the '454 patent in a few ZOLL patents and (2) a ZOLL executive was aware Philips had sued other companies for patent infringement. Br. at 41. These isolated facts did not compel a finding that ZOLL "knew of the patent[s]" in any meaningful way; and even if they did, the jury was not obligated to make the leap that ZOLL knew it was actually performing "***acts*** [that] constituted infringement" of those patents, as required by the knowledge element. *Fujitsu*, 620 F.3d at 1330.

Philips also relies heavily on the accusation that ZOLL changed its website's description of its defibrillators because it allegedly knew that they infringed Philips's patents. Br. at 42. But ZOLL presented the jury with an alternate explanation for the change: ZOLL believed that "Philips was obviously taking this out of context … ***misinterpreting*** [the earlier web site language] to mean that …

we were doing something that they had patented." A1981:17-82:3. Philips strains even further by contending that ZOLL's introduction of an indisputably non-infringing alternative was evidence from which the jury was obligated to infer that ZOLL had knowledge of infringement. Br. at 42; A18981; A2453:14-A2455:1. ZOLL provided contrary evidence—including testimony that the new product actually employed a "better way" of measuring impedance that was "slightly more accurate" (A2436-37)—and thus it was perfectly reasonable for the jury to reject Philips's proffered inference.

Moreover, the jury considered and implicitly rejected Philips's argument that ZOLL copied Philips's technology and accepted ZOLL's evidence of independent conception. For example, ZOLL filed applications for patents on its unique biphasic waveform in 1996, almost fourteen years before this lawsuit began and before the '454 patent even issued. A1950:5-51:23. ZOLL announced the results of clinical studies showing the unique improved efficacy of ZOLL's waveform over monophasic waveforms in 1999, the same year it publicly announced the incorporation of its waveform into its biphasic M Series defibrillator. A18677-78. From the very beginning, ZOLL differentiated its rectilinear biphasic waveform from a typical biphasic truncated exponential waveform, which Philips's patents describe. A18988-93. Only ZOLL's biphasic waveform—not Philips's—is cleared by the FDA to be promoted as superior to

monophasic. A1953:3-14. Indeed, Philips's own design engineer candidly admitted that Philips's waveform "is not up to the task of competing directly against the other biphasic waveforms," including ZOLL's "improved" waveform. A1332:13-33:17; A1337:7-38:10; A16045-49.

Philips's long delay in suing ZOLL also supports the jury verdict. ZOLL openly publicized the details of its waveform in peer-reviewed articles and ZOLL patents as early as 1998. A8489-510; A8905-25; A14774-809; A18039-A18125; A24-25. One of the authors of these articles later joined Philips. A14908-12; A2066-67; A23. Employees from ZOLL and Philips were in regular contact and even collaborated on the companies' shared business goals relating to waveform technology. A17300-01; A1961:2-62:2, A2057:17-58:8; A24-25. Philips monitored ZOLL's business activities for years, including ZOLL literature and products whose functionality was "self-evident" (e.g., self-test). A14839-60; A14865-907; A19043-44; A25-A29. Philips even evaluated both ZOLL's technology and Heartstream's technology before acquiring the asserted patents in 2001. A2021:8-17. Nevertheless, Philips waited almost seven years even to suggest to ZOLL that some products might infringe certain Philips patents. A1978:21-22. If, for all these years, even Philips evidently did not think that ZOLL infringed, the jury certainly had sufficient basis to conclude that ZOLL itself lacked the requisite knowledge of infringement. Indeed, ZOLL CEO Mr. Packer testified he was

"astounded" when Philips brought suit after such an extended period without any complaint from Philips given the transparency of ZOLL's activities in the industry. A1966:9-22.

In short, the jury reasonably rejected Philips's proposed inferences regarding ZOLL's supposed knowledge of infringement, and there is no basis to reverse the jury's resolution of these factual disputes.

### 2. The Jury Was Not Required To Accept Philips's Licensing Position As Conclusive Evidence Of ZOLL's Knowledge

The only other purported evidence of knowledge Philips points to is the parties' licensing discussions between 2008-2010. Philips again urges this Court to make inferences *against the jury verdict*. But here, too, the jury verdict is amply supported. For example, ZOLL's CEO testified without rebuttal that Philips based its demand for a license on the sheer volume of patents it owned and the imagined likelihood that ZOLL "must be violating some of them." A1978:21-79:12. Philips later identified "ten Philips patents" from its stack of patents, but did not even include the '454 and '905 patents in this group. A12706-13. ZOLL disputed that it was liable for infringement of any patents on this shorter list. A12706. After almost two years of licensing negotiation, Philips abandoned the vast majority of its accusations for the more than 100 patents on its original list and brought suit on a new subset of 15 patents. A5; A191; A132. Even then, Philips later abandoned its infringement allegations for most of these asserted patents prior to trial. A104-11.

Of the remaining patents, the jury concluded that ZOLL did not infringe two patents and certain claims of the others, and Philips has not even challenged those findings on appeal. A105-A113.

This history demonstrates why Philips's "knowledge" argument defies logic. If knowledge of Philips's mere *accusations* mandates a finding that ZOLL had the requisite knowledge of infringement, as Philips urges, then ZOLL would be said to have had "knowledge" of numerous acts of infringement that indisputably never occurred. Thus, Philips's shifting *accusations* of infringement cannot conclusively establish ZOLL's knowledge of *actual* infringement. Indeed, the jury had a reasonable basis to conclude that even *Philips* did not know which of its patents ZOLL might infringe.

### 3. No Cases Support Philips's Argument

Philips's argument that a bare accusation of infringement necessarily mandates, as a matter of law, a directed verdict on the knowledge requirement of § 271(c) misstates the law and would eviscerate the right to a jury trial. Br. at 39-43. Most of the cases that Philips cites are decisions *affirming* a finding of contributory infringement rather than overturning a jury verdict of no contributory infringement. *See, e.g.*, *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1355 (Fed. Cir. 2010) (affirming finding of contributory infringement); *Aro II,* 377 U.S. at 491 (affirming finding of contributory infringement for some time periods and

remanding for "finding of fact" regarding defendant's knowledge for others). This procedural distinction is significant, as facts that might prove sufficient to *support* a finding of contributory infringement do not necessarily require *overturning* a finding of no contributory infringement.

For example, in *Aro*, the district court had entered a judgment of contributory infringement against the accused infringer ("Aro"). 377 U.S. at 479. Aro had admitted that it knew that purchasers of its accused fabric "intend to use the fabric for replacement purposes on automobile convertible tops which are covered by the claims of respondent's combination patent." *Aro I*, 365 U.S. at 341. Further, there was no dispute that the only use for the component that Aro sold was unlawful infringement because these specific replacement fabrics were only compatible with unlicensed tops. *Aro II*, 377 U.S. at 480. In fact, Aro admitted that "it knew that its replacement fabrics were especially designed for use in the [unlicensed] tops and were not suitable for other use." *Id.* at 488. On that factual record, the Court's affirmance of a finding of contributory infringement was unremarkable. However, there is nothing in *Aro II* that demands overturning a jury verdict of no contributory infringement, especially in the absence of any similar admissions or facts proven in this case.

In fact, the only case Philips cites involving a reversal of a jury verdict finding no indirect infringement was in a case of induced (not contributory)

infringement, where the defendant conceded that the only disputed issue was whether there was any underlying direct infringement. *See Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1302-05 (Fed. Cir. 2002). The Court resolved that case as a matter of law because the defendant was judicially estopped from denying predicate direct infringement. Contrary to Philips's assertion, *Chemque* does not provide any precedent for overturning the jury's verdict regarding a defendant's state of mind.

#### 4. ZOLL Cannot Be Liable For Contributory Infringement Prior To Notice Of Philips's Accusations

Philips's "evidence" of knowledge suffers from yet additional defects. Even if Philips's 2009 licensing letter (A12706) were held to establish some partial knowledge of infringement, this could not apply to any alleged acts of infringement *before* 2009, or to any patents or products not mentioned in the letter. For example, the July 2009 letter cannot establish ZOLL's knowledge of the '454 or '905 patents because it does not even mention those patents. A12706-13. *See, e.g.*, *Aro II*, 377 U.S. at 479 (vacating judgment of contributory infringement for sales of accused components made before defendant had knowledge of patent); *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1447 (Fed. Cir. 1990) (no contributory infringement liability before defendant had knowledge of patent). Furthermore, the letter mentions only ZOLL's AEDs, not its hospital defibrillators. A12706. Indeed, Philips did not even accuse ZOLL's hospital defibrillators of

infringement until April 2012. A5801 ¶17. Under any scenario, Philips is not entitled to judgment of contributory infringement as to ZOLL's hospital defibrillators based on any acts by ZOLL before April 2012.

#### 5. The Jury Was Permitted To Find No Contributory Infringement Based On ZOLL's Well-Founded Good Faith Belief In Non-Infringement And Invalidity

Finally, although the arguments presented above are by themselves more than sufficient to support the jury's verdict of no contributory infringement, that finding is further strengthened by ZOLL's presentation of robust, good-faith defenses of non-infringement or invalidity (or both) for every claim that Philips asserted at trial. *See, e.g.*, A2149:7-357:3; A2613:15-A2720:4; A2808:10-945:23. As the Federal Circuit has held, "[i]t is not reasonable to assume that merely because a defendant is aware of the existence of a patent, he intended to infringe it." *Commil USA, L.L.C. v. Cisco Sys., Inc.*, 720 F.3d 1361, 1368 (Fed. Cir. 2013), *cert. granted by* 135 S. Ct. 752 (2014); *cf. Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (section 271 codified with "no substantive change" the common law contributory infringement doctrine, which required intent to aid and abet the commission of a tort by another).

The jury was entitled to credit testimony establishing that ZOLL had a reasonable, good-faith belief of non-infringement or invalidity for each claim at issue on appeal. ZOLL's CEO expressly stated: "We do not believe that we

infringe." A1981:9. Indeed, ZOLL presented significant evidence and argument in support of its defenses at trial, including the non-infringement and invalidity defenses set out in this Brief. The jury implicitly, and reasonably, found in favor of ZOLL on the knowledge issue. *See Agrizap*, 520 F.3d at 1342 ("[E]ven when the jury is given an essentially black box verdict form … we presume all factual disputes were resolved in favor of the verdict."). For this reason, as well, the judgment of no contributory infringement should be affirmed. *See Ecolab*, 569 F.3d at 1351 (affirming denial of JMOL because "the jury had substantial evidence from which it could have reasonably concluded that [defendant] … lacked the required intent" to indirectly infringe based on non-infringement and invalidity defenses). Finally, Philips's failure to appeal the jury's verdict of no induced infringement further confirms the jury's conclusion that Philips failed to establish the requisite state of mind for indirect infringement. *See Accenture Global Servs. v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013) (failure to appeal one issue on appeal meant underlying findings were "final and conclusive" as to related, appealed issue).

### B. Philips Failed To Prove The Absence Of Substantial Non-Infringing Uses

The jury also had a sufficient basis to find that Philips failed to prove the absence of substantial non-infringing uses for the accused products. This shortcoming provides another independent basis for affirming the jury's verdict of

no contributory infringement. It was Philips's burden to present evidence sufficient to establish this element of contributory infringement. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1362-63 (Fed. Cir. 2012). Philips failed to meet this burden.

With respect to the waveform method claims, the parties agreed at trial that the accused ZOLL products could provide a variety of different defibrillation shocks after the test pulse. For example, lower impedance patients would receive a "rectilinear" waveform with a jagged initial phase as produced by the "DAC" component:

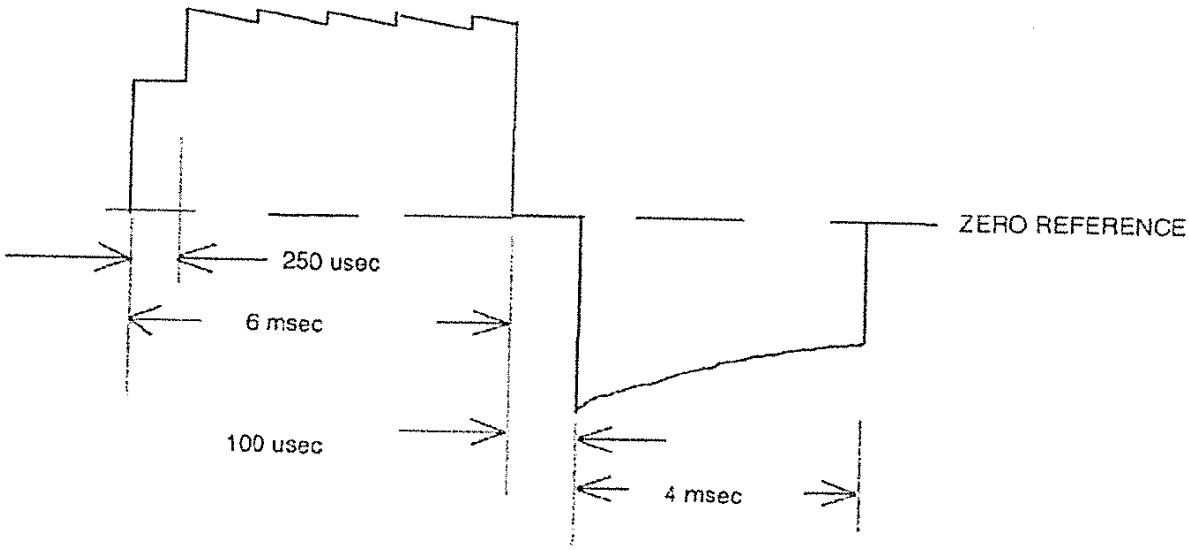



FIGURE 1. Rectilinear Biphasic Waveform
(default energy and impedance = 50 ohms)

Figure is not to scale

A6740; *see also* A2614:6-41:10; *see also* A14774-93; A2391:6-8; A2397:9-401:2; A1944:12-46:2; A1947:23-48:11; A1950:5-52:11; A1953:3-55:3; A1957:12-58:16; A1993:20-94:14; A1663:7-20; A18988-93.

By contrast, a higher impedance patient would receive a standard truncated exponential waveform:

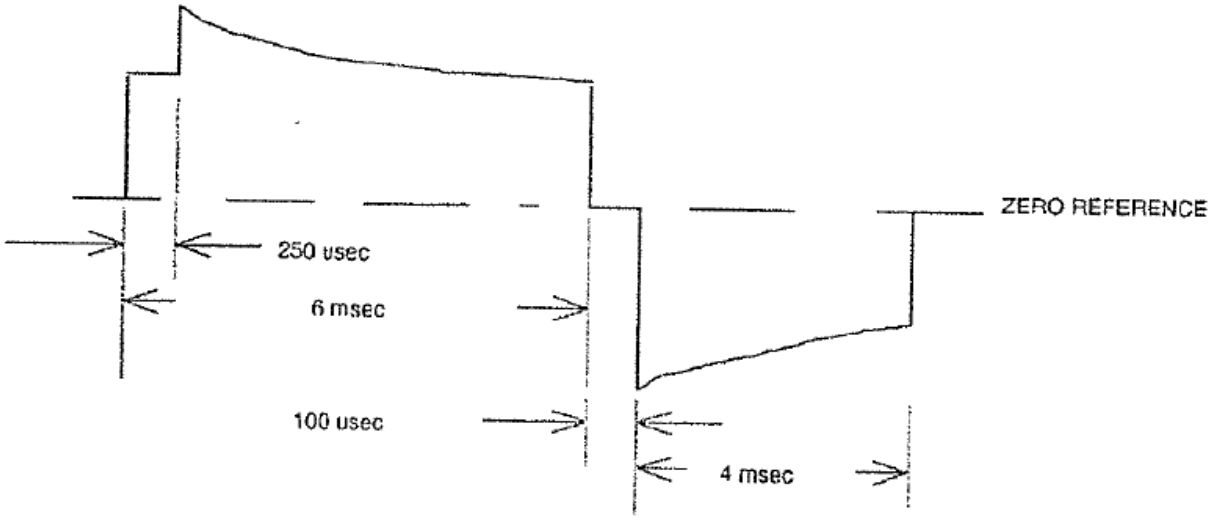



FIGURE 2. Rectilinear Biphasic Waveform
(highest energy and impedance > 85 ohms)
Figure is not to scale

A6741; *see also* A1975:6-20; A2631:8-34:5.

The record supports a finding that ZOLL's rectilinear waveform constituted a substantial non-infringing use with respect to the waveform method claims, which require "discharging *the* energy source *across* the electrodes." A391; A376. ZOLL presented evidence that a POSITA considers actions "across" a circuit component to span only from one side of the component to the other, without any

other intervening component that would absorb appreciable levels of energy. A2700:22–01:23; *see also* A1631:9–14; A390 at 5:13-18, 6:5-10.

There was ample evidence for the jury to conclude that, in the case of ZOLL's rectilinear waveform, the entire energy source is not discharged "across the electrodes" due to the DAC. A1738:8–39:8; A1739:24–40:5; A1742:3–10; A2616:4–8; 2632:9–14; A2635:3–6. As Philips's own expert agreed, the resistors in the DAC absorb appreciable levels of energy resulting in the jagged rectilinear waveform—indeed, that is their very purpose. A1738:8–39:8. In Philips's patents, in contrast, the full energy is delivered across the electrodes to generate an exponentially decaying waveform. A2625:15–26:18; A2631:8–19. The jury therefore had a sufficient basis to find that ZOLL's rectilinear waveform presented a substantial non-infringing use for the accused products, even if ZOLL's truncated exponential waveform did not.

Philips likewise failed to prove a lack of substantial non-infringing uses with respect to the self-test patents. For example, Philips's expert opined ZOLL's products were *capable of* performing tests on a "first" and "second periodic schedule" in accordance with claim 7 of the '460 patent (*see* A1883:6-84:19). However, this was a user-configurable option (*e.g.*, A12220), and there was no evidence that performing tests on a *single* periodic schedule would involve any components and circuitry distinct from what Philips had accused. As another

example, evidence presented at trial demonstrated that the accused self-tests could be performed as part of a manual "power-on" procedure, as opposed to "automatically … prior to any attempted use of the defibrillator" ('374 claims 42, 67-68; '460 claim 7). A1876:1-22; A1822:3-23:8; A1889:12-24; A16886; A12480; A12636-37; A11109; A1885:23-86:12; A5097:7-19. The jury thus had ample reason to find substantial non-infringing uses for the accused functionality of ZOLL's defibrillators.

Philips did not present evidence that any of these non-infringing uses were insubstantial: "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *See Toshiba*, 681 F.3d at 1362. Nor was there any evidence that these non-infringing uses comprise specific hardware and software that are separate and distinct from allegedly infringing features. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327-28 (Fed. Cir. 2009) (no contributory infringement where non-infringing aspects of product were not shown to be "merely additional, separable features of the device").

The scant evidence Philips cites in its brief in no way mandates a finding of no substantial non-infringing uses. Philips relies primarily on a few lines of conclusory testimony from its expert, who walks through a few elements of § 271(c) without any supporting analysis or evidence. A1688:4-89:7. This "evidence" hardly suffices to conclusively satisfy Philips's burden despite a

contrary jury verdict. Similarly, Philips's argument that customers may shock patients or conduct self-tests in the manner that Philips contends is infringing (Br. at 37-39) fails to affirmatively demonstrate the complete absence of other, non-infringing uses. *Toshiba*, 681 F.3d at 1363 ("Recommending one use over another does not mean the non-recommended use is not substantial.").

### C. Philips Failed To Prove Predicate Acts of Direct Infringement By Others

Liability for contributory infringement also requires proof of predicate acts of direct infringement by another. *Limelight*, 134 S. Ct. at 2117 & n.3; *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006) ("the patentee always has the burden to show direct infringement for each instance of indirect infringement"). Here, the verdict form asked the jury whether Philips proved that "others directly infringed the [Philips method claims] through use of ZOLL's defibrillators, and that ZOLL **knowingly contributed** to such infringement," and the jury answered, "No." A105-109 (emphasis in original). This is a further independent basis for rejecting Philips's bid for judgment of contributory infringement.

Philips failed to offer evidence at trial of actual performance of Philips's asserted method claims by third parties. Instead, Philips points to a handful of citations to the effect that ZOLL's products are capable of being used in an infringing manner and are generally used "as intended." Br. at 20-21, 37-38. This

vague testimony is insufficient to *require* overturning the jury's verdict of no contributory infringement and entering a judgment of contributory infringement. For example, as to claim 7 of the '460 patent, it was more than reasonable for the jury to conclude that Philips had failed to prove direct infringement by others, as Philips never presented evidence compelling a conclusion that any ZOLL customers actually chose to use two periodic schedules with the accused self-tests. Nor did Philips present evidence that would have inexorably required the jury to draw the inference that customers must have necessarily used the ZOLL products to deliver therapy with an actually infringing waveform as opposed to a non-infringing waveform (*see* Section I.B above). *See Acco Brands, Inc. v. Aba Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1272 (Fed. Cir. 2007) (reversing verdict of induced infringement because plaintiff failed to show either that accused device necessarily infringed or specific instances of direct infringement).

On the self-test method claims, Philips did not present evidence that customers must have chosen configurations of the ZOLL products that employed automatic and periodic self-tests as opposed to power-on self-tests only. Indeed, the trial record included evidence demonstrating why users would prefer to use basic manual testing over automated testing (*e.g.*, to promote familiarity with defibrillators and avoid battery depletion, *see* A1941-42, A1884:6-8), and even Philips concedes that users could decide whether or not to use automated self-

testing with ZOLL's products (A1899). Moreover, contrary to Philips's argument (Br. at 38, citing A2909-10), ZOLL never conceded direct infringement of these claims, as mere evidence regarding the capability of a *product* cannot establish infringement of a *method* claim without evidence that the product actually performed the claimed steps. Thus, the trial record provided ample basis for the jury to conclude that Philips failed to prove direct infringement by others.

Though Philips appears to argue that there was evidence sufficient for the jury to have drawn the inference that others had actually performed the claimed methods, that is not the proper standard on appeal from an adverse jury verdict. The Federal Circuit has held parties to a strict standard on this issue: "[i]f it was inconceivable to [the patentee] that the accused features were not practiced ..., it should have [had] no difficulty in meeting its burden of proof and introducing testimony." *Mirror Worlds*, 692 F.3d at 1362. Judgment of no contributory infringement should be affirmed for this reason.

## II. Philips Failed To Prove By Clear and Convincing Evidence That The '526 Patent Is Indefinite

The '526 patent claims a gel-covered electrode that has a relatively high impedance to reduce the risk of patient burning. A343-51; A2107:4-12:16; A2185:2-87:8. The claims require a defibrillation electrode with several structural characteristics, such that when the electrode is tested under a specified bench test, which requires applying a 200 Joule pulse to the electrode, it produces a resistance

greater than 1Ω. A350 at col. 9:17-25. The bench test limitation was added during prosecution to overcome an indefiniteness rejection. A17028-159; A5107:12-10:10. The examiner found all claims definite because of this limitation. *Id.*

The jury found that eight Philips electrode types infringe ZOLL's '526 patent and that the asserted claims are not invalid. A115. The jury heard extensive testimony from ZOLL's expert Dr. Halperin regarding the tests he performed on Philips's accused products. *See, e.g.*, A2190:21-92:18; A2195:11-97:6; A2201:6-11:19, A5152:12-59:21; A19010-27. Dr. Halperin's tests showed that all of the accused Philips electrodes produced a resistance greater than 1Ω in the 200 Joule test specified by the '526 patent. *Id.* Indeed, when Philips's expert Dr. Efimov tested the accused Philips products according to the test actually specified in the patent, his tests generated the same results. A5076:2-25; A12106-07. The parties' respective experts testified at length on the indefiniteness issues Philips raises on appeal and the jury reasonably credited the testimony of ZOLL's expert. Philips improperly seeks to have this Court reweigh the evidence.

### A. The Jury Could Reasonably Reject Philips's Test Results Because They Were Obtained Using 150 Joules Of Energy, Not The Claimed 200 Joules

At trial, ZOLL's expert and fact witnesses testified that a POSITA would test electrode impedance at a laboratory bench at room temperature and that Philips's electrodes infringed the '526 patent when tested as required by the

claims. *See, e.g.*, A2116:20-21; A2336:1-21; A2338:1-40:24; A2352:8-25; A2353:1-54:6; A5114:12-19; A2192:1-22; A2195:11-96:23; A2205:1-10; A2206:8-23; A2207:13-24; A2209:14-24; A2210:21-11:6. On appeal, Philips does not challenge the jury's determination that the impedance testing must take place at room temperature.

Instead, Philips asks this Court to overturn the jury's decision not to credit its expert's test results even though its expert's tests did not comply with the bench test specified in the asserted claims. A5113:9-16; A2355:1-7; A12011; A12110. Philips's expert performed tests at 28° Celsius using a 150 Joule pulse. *Id.* But the asserted claims specify using a 200 Joule pulse for the bench test. A350 cl. 1, 24; A349 at 7:13-23. Philips's expert never explained why he diverged from the parameters claimed in the '526 patent. Moreover, when Philips's expert performed his tests at the claimed 200 Joules (conducted at 15° and 25° Celsius), he obtained resistances greater than 1Ω. A5074:5-75:15; A5076:2-13; A2345:19-46:4; A2197:7-17; A12106-07. The jury was entitled to reject the test results and testimony of Philips's expert. *See, e.g.*, *Layne Christensen Co. v. Bro-Tech Corp.*, 871 F. Supp. 2d 1104, 1111 (D. Kan. 2012) (denying JMOL motion of non-infringement because jury was "free to reject" defendant's expert's experiment because it "did not exactly replicate" the conditions at issue).

At most, the jury was faced with competing test results from opposing experts. Competing tests results do not render a patent claim indefinite; they simply present a fact question for the jury. *See, e.g.*, *ADC Telecomms., Inc. v. Switchcraft, Inc.*, 281 F. App'x 989, 992 (Fed. Cir. 2008) (dispute over "proper testing method" was "a factual question that the district court properly submitted to the jury").

Philips erroneously analogizes the '526 claims to the "fragile gel" limitation of *Halliburton Energy Services v. M-I L.L.C.*, 514 F.3d 1244, 1246-55 (Fed. Cir. 2008). Br. at 53-54. However, Halliburton's proposed construction defined a "fragile gel" using unbounded, subjective terms. *Id.* at 1250-51. The Court held that the claims were indefinite because Halliburton's proposed constructions failed "to identify the degree of the fragility of its invention." *Id.* at 1253-54. Similarly, in *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332 (Fed. Cir. 2003), the Court affirmed a finding of indefiniteness where the intrinsic record failed to specify any particular sample preparation method at all that could be used to measure the claimed parameter. *Id.* at 1339-40. Here, in contrast, ZOLL's claims specify a specific bench test, providing "numeric limitations as to a physical property" (1Ω) and a "formula for calculating that property" (using a 200 Joule pulse)—approaches that the Court specifically endorsed in *Halliburton* to avoid indefiniteness. 514 F.3d at 1252, 1255-56.

### B. Philips's "Number Of Shocks" And "Age of the Electrode" Arguments Are Red Herrings

Philips next argues that the '526 patent claims are indefinite because some electrodes' resistance can increase as the number of shocks increase. Br. at 50-52. This argument is a red herring. As Dr. Halperin's test results established, the accused Philips products produce resistances well over 1Ω—and therefore infringe—from the very first shock. And Philips's own expert agreed that resistance did not go down as the number of shocks increased—it only went up—and therefore the accused Philips products remained within the scope of the claims of the '526 patent regardless of the number of shocks applied. A5123:25-24:20. The jury was entitled to credit Dr. Halperin's testimony.

Philips points to a document regarding ZOLL's own internal testing, which for some Philips products indicated resistances under 1Ω in several measurements. A11321-22; A5078:15-A5080:23. But neither ZOLL nor Philips contend that these Philips products infringe the '526 patent. A5079:11-16 (anything below 1Ω "does not infringe"). Philips does not explain how ZOLL's testing of non-infringing (and non-accused) products proves indefiniteness.

Furthermore, neither expert contended that bench tests results should not count until multiple shocks are applied. To the contrary, both experts shocked several times simply to confirm the reliability of their test. A19010-15 (Halperin shocked six times); A5077:20-21 (publishing A5915 (Dr. Halperin: multiple

shocks ensured consistency)); A5078:12-14 (Efimov shocked three times). Philips is straining to interject indefiniteness where there is none. *Cf. Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (rejecting claim construction that would render claims indefinite).

Philips's "age of the electrodes" argument is even more of a red herring. Electrodes have an expiration date, and Philips concedes that testing had to occur "within [the] shelf life" of the electrode. A19010-27; Br. at 51. Dr. Halperin tested Philips electrodes that were not expired. A19010-27; A2353:17-54:6. There is no evidence in the record that an unexpired electrode's age matters for an infringement determination. Indeed, Philips's sole example of resistance increasing over time was an electrode that was found to have a resistance greater than 1Ω from beginning to end. A5081:2-82:25; A11292. Philips's own expert did not do age-based testing of Philips's electrodes. A5126:8-18. Nor is there any suggestion in the record that a POSITA would not know to test an unexpired electrode.

Finally, and fundamentally, "[t]he test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340-41 (Fed. Cir. 2005). Here, there is substantial evidence that a POSITA would readily understand how to conduct the claimed bench test, and thus

understand the bounds of the '526 claims. *See, e.g.*, A2116; A2336-40; A2352:8-25; A5164:14-25. There is no basis for reversing the judgment of no invalidity of the asserted claims of the '526 patent.

## III. Philips Is Not Entitled To A New Trial On The '526 Patent Based On One Portion Of The Jury Instructions On Indefiniteness

Philips's request for a new trial based on the Supreme Court's *Nautilus* decision also lacks merit. Br. at 57-60. Philips bases its challenge on a single sentence in one portion of the jury instruction on indefiniteness and ignores the context of the entire instruction. The District Court also instructed that "[p]atent claims must be sufficiently clear that a person of ordinary skill in the field of the invention reading them is able to determine what the claims cover and what they do not cover." The District Court further instructed that Philips could prevail on its indefiniteness challenge by proving that "a person of ordinary skill in the art would not understand what is and is not covered by the claims of Zoll's patent." A161:24-62:21. These instructions are consistent with the Supreme Court's *Nautilus* formulation that a patent's claims must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus*, 134 S. Ct. at 2129.

The single reference to this Court's then-current "insolubly ambiguous" phrasing, in the overall context of an otherwise correct instruction, does not entitle Philips to a new trial. *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1118 (Fed. Cir. 2008) (holding that "[w]hile [a portion of the trial court's] instruction might

violate [Supreme Court's] *KSR* [decision] if it were the only instruction," the district court's instructions read in their entirety were not erroneous); *Sulzer Textile*, 358 F.3d at 1365 (affirming denial of motion for new trial based on a "single mistaken reference in the jury instructions," because the "jury instructions, viewed in their entirety and considered in the context of the trial as a whole, presented the correct legal standard for infringement to the jury.").

A new trial is particularly inappropriate on this record because Philips has failed to establish any prejudice from the instruction as given. Not a single trial witness ever referred to the "insolubly ambiguous" formulation—and for good reason. The question for the jury was not whether any term in the '526 patent claims were too ambiguous to be amenable to construction. Rather, the question was whether the claims were sufficiently clear that a POSITA could determine what the claims cover and what they do not—just as the District Court instructed, consistent with *Nautilus*.

## IV. The District Court Did Not Abuse Its Discretion By Excluding Documents Philips Offered Without Adequate Foundation

Philips requests a new trial on the '526 patent by arguing that the District Court "Improperly Excluded Evidence of the Marquette Responder 1200 Electrode Prior-Art Device." Br. at 61. Philips appears to contend that the District Court held "without explanation" that the Marquette Responder 1200 Electrode was not prior

art and therefore erred by categorically excluding evidence regarding these electrodes. *Id.* at 61-62. This assertion is contrary to the record.

Philips never offered a Marquette 1200 electrode as evidence. A5009:13-10:11. Instead, Philips attempted to establish sales of the electrodes via deposition testimony and to establish "the operation of" those electrodes via two third-party 510(k) submissions. *Id.* The District Court had previously ruled that Philips had failed to establish proper foundation for these particular 510(k) submissions and confirmed that it was not reconsidering that ruling. A5009:25-10:1. Because Philips failed to proffer any competent evidence regarding the operation of the Marquette 1200 electrode, Philips did not read to the jury the deposition testimony regarding the sales of those electrodes. A5009:10-10:8.

Philips's suggestion that the District Court abused its discretion by excluding these 510(k) submissions also fails. Philips contends that the District Court "found that there was a blanket prohibition on using 510(k) documents as prior art." Br. at 60. But the Court never made any such ruling. Indeed, the District Court received other 510(k) submissions into evidence. A2955:6-17. Philips simply failed to provide a foundation that *these particular 510(k) submissions* are prior art "printed publications." A5939-41.

Establishing that a document qualifies as a "printed publication" under 35 U.S.C. § 102 requires "a satisfactory showing that such document has been

disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008). The District Court did not abuse its discretion in determining that Philips made no such showing for these 510(k) submissions.

Philips primarily relies on evidence that these documents were no longer confidential. Br. at 63-64. However, the absence of legal prohibitions against disclosure of a document does not establish that the document was "publicly available" as a printed publication prior to the critical date of the '526 patent. Phillips points only to a FOIA *request* submitted on November 21, 1991. A5586. But the information was not disseminated until December 14, 1992, months *after* the May 1, 1992 filing date of the '526 patent. A5585. There is thus no evidence that these 510(k) submissions *themselves* were either "disseminated or otherwise made available" to persons of ordinary skill in the art prior to the filing date of the '526 patent.

Further, to the extent Philips contends that one of the submissions constitutes evidence of the features of the Marquette 1200, Br. at 62, it was properly excluded as containing inadmissible hearsay. *See* Fed. R. Evid. 802. Philips failed to provide a proper foundation for admitting the test data contained in the 510(k) submission, including who performed the tests, how the tests were

performed, or whether the tests were accurate. A5947-50, 5954-56; A1007:10-16; A3005:18-07:19; A5939-41; A5005:1-11. Philips failed to establish that the District Court abused its discretion by excluding these documents or by denying Philips a new trial based on their exclusion.

## CONCLUSION

For the foregoing reasons, ZOLL requests that this Court:

(1) reverse the District Court's judgments of:

   (a) ZOLL's direct infringement of the asserted claims of the '905, '454, '212 and '460 patents and all but claim 43 of the '374 patent; and

   (b) no invalidity of the asserted claims of the '374, '460 and '905 patents; and

(2) affirm the District Court's judgments of:

   (a) no contributory infringement by ZOLL of the asserted claims of the '454, '905, '374 and '460 patents; and

   (b) the judgment of no invalidity of the asserted claims of the '526 patent.

Respectfully submitted,

Dated: February 9, 2015 */s/ David I. Gindler*

David I. Gindler
Alan J. Heinrich
David C. McPhie
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276

Counsel for Defendant-Appellee and Cross-Appellant ZOLL MEDICAL CORPORATION

**UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

**CERTIFICATE OF SERVICE**

---

I certify that on February 9, 2015, ZOLL's Principal and Response Brief was filed electronically using the CM/ECF system and served via the CM/ECF system on counsel for Plaintiff-Appellant as follows:

J. Michael Jakes
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413

Dated: February 9, 2015 */s/ David I. Gindler*

David I. Gindler
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276
Phone (310) 277-1010
Fax (310) 203-7199
dgindler@irell.com

## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or FRAP 28.1(e). The brief contains 16,468 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or FRAP 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Word 2010 in size 14 Time New Roman font.

Dated: February 9, 2015 */s/ David I. Gindler*

David I. Gindler
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276
Phone (310) 277-1010
Fax (310) 203-7199
dgindler@irell.com

Counsel for Defendant-Appellee and Cross-Appellant ZOLL MEDICAL CORPORATION

# ADDENDUM

1. **Final Judgment**
2. **D.I. 691 Order Denying JMOL**
3. **D.I. 106 Markman Order**
4. **35 U.S.C.§ 271**

**United States District Court**
**District of Massachusetts**

| | | |
|---|---|---|
| **KONINKLIJKE PHILIPS N.V. and PHILIPS ELECTRONICS NORTH AMERICA CORPORATION,** | ) | |
| **Plaintiffs/ Counter-Defendants,** | ) | **Civil Action No. 10-11041-NMG** |
| **v.** | ) | |
| **ZOLL MEDICAL CORPORATION,** | ) | |
| **Defendant/ Counter-Claimant.** | ) | |

**ORDER OF FINAL JUDGMENT AS TO LIABILITY**

In accordance with the jury verdict of December 19, 2013, it is hereby **ORDERED:**

1) Judgment shall enter in favor of plaintiffs/counter-defendants Koninklijke Philips N.V. and Philips Electronics North America Corporation (collectively, "Philips") and against defendant/counter-claimant ZOLL Medical Corporation ("ZOLL") on Count 1 of Philips's Second Amended Complaint (Docket No. 36) and on Counts 1 and 16 of ZOLL's Second Amended Counterclaim (Docket No. 38) to the extent that it is adjudged that Claim 51 of U.S. Patent No. 5,607,454 is infringed by the ZOLL AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators and is not invalid;

2) Judgment shall enter in favor of Philips and against ZOLL on Count 4 of Philips's Second Amended Complaint and on Counts 4 and 19 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 8 of U.S. Patent No. 5,749,905 are infringed by the AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators and are not invalid;

3) Judgment shall enter in favor of Philips and against ZOLL on Count 6 of Philips's Second Amended Complaint and Counts 6 and 21 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claim 7 of U.S. Patent No. 5,800,460 is infringed by the AED Plus and AED Pro defibrillators and is not invalid;

4) Judgment shall enter in favor of ZOLL and against Philips on Count 8 of Philips's Second Amended Complaint and Count 8 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 5 of U.S. Patent No. 5,836,978 are not infringed by the AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators but judgment shall enter in favor of Philips and against ZOLL on Count 23 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 5 of U.S. Patent No. 5,836,978 are not invalid;

5) Judgment shall enter in favor of Philips and against ZOLL on Count 9 of Philips's Second Amended Complaint and Counts

9 and 24 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 42, 67 and 68 of U.S. Patent No. 5,879,374 are infringed by the ZOLL AED Plus, AED Pro and R-Series defibrillators and are not invalid, Claim 43 is infringed by the AED Plus, AED Pro, R Series and X Series defibrillators and is not invalid, and Claims 66 and 73 are not invalid but judgment shall enter in favor of ZOLL and against Philips to the extent that it is adjudged that Claim 66 is not infringed by the AED Plus, AED Pro, E Series and R Series and Claim 73 is not infringed by the AED Plus and AED Pro;

6) Judgment shall enter in favor of Philips and against ZOLL on Count 10 of Philips's Second Amended Complaint and Counts 10 and 25 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 1 and 5 of U.S. Patent No. 6,047,212 are infringed by the AED Plus, AED Pro, R Series and X Series defibrillators and are not invalid;

7) Judgment shall enter in favor of ZOLL and against Philips on Count 13 of Philips's Second Amended Complaint and Count 13 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 1 and 7 of U.S. Patent No. 6,356,785 are not infringed by the AED Plus, AED Pro, E Series and X Series defibrillators but judgment shall enter in favor of Philips and against ZOLL on Count 28 of ZOLL's Second Amended

Counterclaim to the extent that it is adjudged that Claims 1 and 7 of U.S. Patent No. 6,356,785 are not invalid;

8) Judgment shall enter in favor of ZOLL and against Philips on Count 1 of ZOLL's Complaint (Case 1:10-cv-11162, Docket No. 1) and Counts 1 and 6 of Philips's Counterclaim (Docket No. 13) to the extent that it is adjudged that the Philips HeartStart FR2 Infant/Child Pads, HeartStart Infant/ Child Smart Pads and HeartStart Adult Smart Pads infringe Claims 1, 8, 9, 11, 12, 19, 24 and 25 of U.S. Patent No. 5,330,526; the Adult Plus MFE Electrode Pads and Multi-Function Pediatric Defibrillation Electrodes infringe Claims 1, 11, 12, 19 and 24; The HeartStart Adult Preconnect MFE Pads infringe claims 1, 9, 11, 12, 19 and 24; the Adult Radiotransparent/Reduced Skin Irritation Pads infringe Claims 1, 11, 12, 19 and 24; the Pediatric Radiotransparent/Reduced Skin Irritation Pads infringe Claims 11, 12 and 19; and Claims 1, 2, 3, 8, 9, 11, 12, 19, 23, 24 and 25 are not invalid; but judgment shall enter in favor of Philips and against ZOLL to the extent that it is adjudged that Claims 2, 3 and 23 of U.S. Patent No. 5,330,526 are not infringed by any of the aforementioned devices and Claim 1 is not infringed by the Pediatric Radiotransparent/Reduced Skin Irritation Pads;

9) Judgment shall enter in favor of ZOLL and against Philips on Count 2 of ZOLL's Complaint and Counts 2 and 7 of

Philips's Counterclaim to the extent that it is adjudged that Claims 1 and 4 of U.S. Patent No. 5,391,187 are infringed by the Philips HeartStart XL defibrillator and are not invalid but judgment shall enter in favor of Philips and against ZOLL to the extent that it is adjudged that Claims 1 and 4 are not infringed by the Philips HeartStart MRx defibrillator;

10) Philips's claims for judgment of infringement with respect to U.S. Patent Nos. 5,721,482 (Count 2), 5,735,879 (Count 3), 5,773,961 (Count 5), 5,803,927 (Count 7), 6,178,357 (Count 11), 6,304,783 (Count 12), 6,441,582 (Count 14), and 6,871,093 (Count 15) are DISMISSED;

11) ZOLL's counterclaims for a declaratory judgment of non-infringement with respect to U.S. Patent Nos. 5,721,482 (Count 2), 5,735,879 (Count 3), 5,773,961 (Count 5), 5,803,927 (Count 7), 6,178,357 (Count 11), 6,304,783 (Count 12), 6,441,582 (Count 14), and 6,871,093 (Count 15) are DISMISSED;

12) ZOLL's counterclaims for a declaratory judgment of invalidity with respect to U.S. Patent Nos. 5,721,482 (Count 17), 5,735,879 (Count 18), 5,773,961 (Count 20), 5,803,927 (Count 22), 6,178,357 (Count 26), 6,304,783 (Count 27), 6,441,582 (Count 29), and 6,871,093 (Count 30) are DISMISSED;

13) ZOLL's claims for a judgment of infringement of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED;

14) Philips's counterclaims for a declaratory judgment of non-infringement of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED; and

15) Philips's counterclaims for a declaratory judgment of invalidity of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED.

Dated June 20, 2014

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KONINKLIJKE PHILIPS N.V.
and PHILIPS ELECTRONICS NORTH AMERICA CORPORATION,

Plaintiffs/Counterclaim-Defendants,

v.

ZOLL MEDICAL CORPORATION,

Defendant/Counterclaim-Plaintiff.

C.A. No. 1:10-cv-11041-NMG

**ZOLL MEDICAL CORPORATION'S MOTION FOR JUDGMENT AS A MATTER OF LAW REGARDING NON-INFRINGEMENT, INVALIDITY, AND OWNERSHIP**

ZOLL Medical Corporation ("ZOLL") respectfully requests judgment as a matter of law ("JMOL") on the following:

1. No infringement of the '905 patent (claims 4, 8); '454 patent (claim 51); '212 patent (claims 1, 5); '374 patent (claims 42, 67, 68); and '460 patent (claim 7);
2. Invalidity of the '374 patent (claims 42, 43, 67, 68); '460 patent (claim 7); '454 patent (claim 51); and '905 patent (claims 4, 8); and
3. Philips's failure to prove ownership of the patents asserted against ZOLL as a threshold for any claim of patent infringement.

At the close of evidence, ZOLL moved for judgment as a matter of law, *see* Dkt. No. 537, and now renews that motion pursuant to Federal Rule of Civil Procedure 50(b). In support of this Motion, ZOLL relies on its Memorandum In Support Of Motion For Judgment As A Matter Of Law Regarding Non-Infringement, Invalidity, And Ownership, as well as the Declaration of David C. McPhie and supporting exhibits.

3085234

Motion denied s/ NM Gorton, USDJ 8/13/14

**United States District Court**
**District of Massachusetts**

| | | |
|---|---|---|
| **KONINKLIJKE PHILIPS ELECTRONICS N.V., PHILIPS ELECTRONICS NORTH AMERICA CORPORATION, Plaintiffs,** | ) | |
| **v.** | ) | **Civil No. 10-11041-NMG** |
| **ZOLL MEDICAL CORPORATION Defendant,** | ) | |

**MEMORANDUM & ORDER**

**GORTON, J.**

## I. Background

### A. The Parties

On June 18, 2010, Philips Electronics North America Corporation, a Delaware corporation with its principal place of business in Massachusetts, and its parent company Koninklijke Philips Electronics N.V., a Dutch corporation with its principal place of business in the Netherlands, (collectively, "Philips") filed a patent infringement suit against ZOLL Medical Corporation ("ZOLL"), a Massachusetts corporation with its principal place of business in Massachusetts.

Philips' complaint, in 15 counts, is for infringement of U.S. Patent No. 5,607,454, No. 5,721,482, No. 5,735,879, No. 5,749,905, No. 5,773,961, No. 5,800,460, No. 5,803,927, No. 5,836,978, No. 5,879,374, No. 6,047,212, No. 6,178,357, No.

6,304,783, No. 6,356,785, No. 6,441,582 and No. 6,871,093, which relate to components of automated external defibrillators ("AEDs").[1] Philips seeks a declaration that ZOLL is infringing the patents-in-suit, equitable relief, including an injunction, and monetary damages.

In a related, later-filed case, ZOLL brought suit against Philips for five counts of patent infringement of U.S. Patent No. 5,330,526, No. 5,391,187, No. 5,470,343, No. 5,575,807 and No. RE39,250, which also relate to components of defibrillators and supplemental products, including electrodes and power supplies. ZOLL seeks a declaration that Philips is infringing the ZOLL patents-in-suit, equitable relief, including an injunction, and damages. In August, 2011 the two cases were consolidated.

The parties submitted 35 claims for construction. The Court issued an order requesting that the parties narrow the claims for construction to 16. The Court conducted a Markman hearing on October 25, 2012 at which counsel offered arguments in support of their proposed claim construction of 15 disputed terms. The following is the Court's ruling with respect to those terms.

**B. The Technology**

**1. Philips' '454, '879, '905, and '978 Patents**

Six of Philip's patents ('454, '879, '905, '978, '212 and '927) are referred to as the "waveform patents" because they

[1] Hereinafter each patent will be referred to by its last three numbers.

relate to the electrical signal (or "waveform") that shocks the patient.

External defibrillators deliver energy to a patient's heart via electrodes applied to the surface of the patient's torso. Due to physiological differences among patients, the resistance to the flow of electricity through the tissue between the defibrillator electrodes and the patient's heart ("impedance") varies from patient to patient depending on the conductivity of their tissues. The intensity of the shock delivered to the heart by the defibrillator can also vary depending on that impedance. A shock that is effective to treat a low-impedance patient may not be effective to treat a high-impedance patient.

Prior art defibrillators required the operator to shock the patient first with an energy level appropriate for the average patient. If the first shock did not work, the operator could then raise the energy level and keep trying. The '454, '879, '905 and '978 patents overcome that problem by providing an external defibrillator that automatically compensates for the different levels of impedance in individual patients in real time by measuring the patient's impedence and adjusting the discharge accordingly.

**2. Philips' '212 Patent**

The particular waveform described in the waveform patents above is "biphasic." With a biphasic waveform, the system flips

a switch midway to change from positive voltage to negative. Biphasic waveforms had been used in implanted defibrillators but until this patent there was no circuitry that could generate the biphasic waveform at the higher voltages required by external defibrillators. The '212 patent discloses a circuit that can deliver the biphasic waveform at the higher voltages required by an external defibrillator.

**3. Philips' '374 and '460 Patents**

The '374 and '460 patents ("the self test patents") cover an external defibrillator that can perform self tests to ensure it is functional and ready to use. Prior art external defibrillators were generally designed for hospitals where equipment is frequently tested and maintained. Portable defibrillators designed for a home or office are much less frequently tested and thus might not be functional when needed. The '374 and '460 patents disclose a defibrillator that conducts automatic self tests, some while switched "on" and others while switched "off." After the test, the defibrillator indicates the result "visually and audibly." The patents also describe a "system monitor" that performs the various functions of the self tests.

**4. Philips' '093 Patent**

The '093 patent is directed to a defibrillator that includes an indicator (audible, visual or both) that reports whether the

defibrillator is functioning properly. The indicator can be activated automatically or in response to a "user-triggered inquiry."

**5. Philips' '785 Patent**

The '785 patent is directed to a defibrillator that uses voice and visual prompts to instruct the user on how to perform CPR correctly because the steps of CPR are often forgotten, even by trained professionals. The covered defibrillator also monitors the heart rhythm of the patient to determine whether it is treatable by shock and, if so, prompts the rescuer to deliver CPR and follow the shock protocol.

**6. ZOLL's '187 Patent**

The '187 patent is directed to a semi-automatic defibrillator which has an alarm. In previous defibrillators the alarm was activated by either the heart rate ("averaged QRS rate") or a shock advisory to indicate to the operator whether the electrocardiogram shows an abnormal heart rhythm of the sort that can be corrected by defibrillation shock. The '187 patent is directed to an alarm based on both of these inputs.

**7. ZOLL's '807 Patent**

The '807 patent relates to a power supply that provides an "AC disconnect alarm." Because a defibrillator is used in emergency situations it is crucial that it is charged when needed. Thus, as the patent explains, "to ensure[] that a

battery of the defibrillator will not inadvertently be left uncharged" the power supply "produces an alarm when it is not connected to a source of AC power." Because this alarm would be distracting during actual emergencies, the alarm signal is only produced when the defibrillator is switched off.

**8. ZOLL's '250 Patent**

The '250 patent is related to ZOLL's '526 patent and is directed to an "electrode package." Inside the package is a "conductor" that is

> covered with a water based, conductive adhesive gel that contacts a patient's skin and electrically connects the electrode to the patient.

The package is an "envelope" formed from a sheet of material folded in half that opens like a book. It provides quick and easy access to the electrodes but also protects them when it is closed.

**9. ZOLL's '526 Patent**

The '526 patent is related to the '250 patent and also concerns defibrillation electrodes. These electrodes are gel-covered discs that are placed on the patient's chest. This patent covers a gel arrangement with an electrical resistance that allows for effective shock treatment while also making it less likely that the patient will be burned.

## III. Analysis

### A. Principles of Claim Construction

In analyzing a patent infringement action, a Court must 1) determine the meaning and scope of the patent claims asserted to be infringed and 2) compare the properly construed claims to the infringing device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The first step, known as claim construction, is an issue of law for the court to decide. Id. at 979. The second step is determined by the finder of fact. Id.

The Court's responsibility in construing claims is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001). The meaning of the terms are initially discerned from three sources of intrinsic evidence: 1) the claims themselves, 2) the specification and 3) the prosecution history of the patent. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 83 (Fed. Cir. 1996).

The claims themselves define the scope of the patented invention. See Philips, 415 F.3d at 1312. Claim terms are generally given their "ordinary and customary meaning", which is the meaning that a person skilled in the art would attribute to the claim term. See id. at 1312-13. Even if a particular term

has an ordinary and customary meaning, however, a court may need to examine the patent as a whole to determine if that meaning controls. Id. at 1313 ("[A] person of ordinary skill in the art is deemed to read the claim term ... in the context of the entire patent...."); see also Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) (noting that a court cannot construe the ordinary meaning of a term "in a vacuum"). Ultimately, the correct construction will be one that "stays true to the claim language and most naturally aligns with the patent's description of the invention ...." Id. at 1316 (citation omitted).

> The patent specification is
>
> the single best guide to the meaning of a disputed term [because it may reveal] a special definition given to a claim term that differs from the meaning it would otherwise possess [or contain] an intentional disclaimer, or disavowal, of claim scope by the inventor.

Phillips v. AWK Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The Court should also consult the prosecution history to see how the inventor and PTO understood the patent and to ensure the patentee does not argue in favor of an interpretation it has disclaimed. Id. at 1317.

In the rare event that analysis of the intrinsic evidence does not resolve an ambiguity in a disputed claim term, the Court may turn to extrinsic evidence, such as inventor and expert testimony, treatises and technical writings. Id. at 1314.

Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence is afforded the greatest weight in determining what a person of ordinary skill would have understood a claim to mean. Id. at 1324.

**B. Disputed Terms**

**1. Monitoring/monitoring. . .during** (Philips' '454, '879, '905, '978 Patents)

The dispute centers on whether monitoring must occur continuously throughout the discharge step, as ZOLL contends, or only one or more times during the discharge step, as Philips' contends.

ZOLL requests that the Court adopt the ordinary meaning of monitoring, which it asserts, has a notion of "ongoingness." ZOLL argues that because the "discharge step" (construed below) takes place over time, "monitoring" must also occur over a period time and cannot be only a single measurement during the step. ZOLL further asserts that the '454 patent actually distinguishes prior art models because they merely "measured" patient impedance and did not continually monitor impedance in "real time." As a result, ZOLL requests that the Court construe the term as "sampling on a regular or ongoing basis" because this definition is the term's ordinary meaning according to the American Heritage Dictionary.

Philips, however, argues that ZOLL's reliance on a single dictionary definition ignores the intrinsic evidence. As a

result, Philips requests that the Court adopt the construction that the United States District Court for the Western District of Washington selected in construing "monitoring" as "measuring... one or more times." Koninklijke Philips Elec.s NV v. Defibtech LLC, 397 F. Supp. 2d 1257 (W.D. Wash. 2005).

The Difibtech Court noted that "monitoring" and "measuring" are both used in related Philips patents. Generally, using different terms raises an inference that the terms have different meanings, but that inference is not determinative. Desper Prods., Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1337 n. 3 (Fed. Cir. 1998). The Difibtech Court concluded that because "both measuring and monitoring occur during periods of time" in the Philips patents, there is "little reason to assume that one term excludes single measurements and one does not." Defibtech 397 F. Supp. 2d at 1264. As a result, the Court construed "monitoring" during the discharge step to require only a "single measurement." Id.

The Defibtech Court determined that if "monitoring" were construed as covering only a single measurement, it would require reading out preferred embodiments. Reading out preferred embodiments is an approach that is "rarely, if ever, correct." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). Each of the six waveform patents, discloses an invention the preferred embodiment of which has three "aspects."

Depending on the patient's impedance, one of the three aspects requires only a single measurement. As a result, the patent must cover single measurements as well as ongoing monitoring. Accordingly, this Court adopts the construction "measuring . . . one or more times."

**2. The discharge step/the discharging step**

ZOLL requests that the Court construe "discharge step" to make clear that it is "not a test pulse to measure patient impedance." The Court believes that by requesting the addition of that negative limitation to the claim term, ZOLL is proposing that the Court resolve an infringement question during claim construction. Doing so would contradict the purpose of a Markman hearing because "the role of the district court in construing claims" is not to "read limitations into the claims to obviate factual questions of infringement." Am. Piledriving Equip. v. Geoquip, Inc. 637 F.3d 1324, 1331 (Fed. Cir. 2011). Here, the Court declines to adopt ZOLL's construction. Instead, the Court adopts the plain meaning of the term and construes it to mean "the step of discharging the energy source."

The Court notes, however, that during prosecution the patentee equated "discharge" with "shock" in describing prior art. That suggests that the "discharge step" was not intended to describe every possible delivery of energy from the energy source.

**3. Plurality of electronic switches** (Philips' '212 Patent)

Philips requests that the Court adopt the same construction of this term as did the Court in Defibtech II, which limited the term to the "five-switch configuration disclosed in the specification." Koninklijke Philips Elect. NV v. Defibtech LLC, C03-1322JLR, 2005 WL 3500783, at *4 (W.D. Wash. Dec. 21, 2005) (Defibtech II). Philips asserts that both the patent examiner and the applicants understood a "plurality of electronic switches" to refer to the five-switch circuit in Figure 11.

In Defibtech II the court held that although the patentee disavowed the prior art five-switch configuration contained in the Swanson patent, the "inventors did not...expressly limit the invention to the five-switch configuration that they disclosed in their patent application." 2005 WL 3500783 at *3. At the Markman hearing in the present case both parties agreed that the statements made during prosecution of the '212 patent do not meet the standard for a "clear and unmistakable" surrender necessary to reject the ordinary meaning. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-26 (Fed. Cir. 2003). In Defibtech II the Court relied on extrinsic evidence including an expert declaration and inventor testimony to reach the conclusion that "plurality of switches" could only cover the five switch configuration contained in Figure 11. Neither of those pieces of extrinsic evidence are, however, before this Court which

therefore declines to adopt that construction.

In Defibtech II, Philips argued contrary to its current position, noting that to construe the "plurality of electronic switches" to cover only the five switch embodiment is

> contrary to the plain, ordinary definition of the word plurality, which means two or more. 'Plurality' does not mean 'only five' or 'five or more.'

This Court agrees. Because the ordinary meaning of plurality is clear to a jury, the term does not require construction.

**4. Prior to any attempted use of the defibrillator** (Philips' '374 Patent)

The parties dispute the meaning of "attempted use" and thus disagree over when the self test must occur. The parties do agree that self tests performed while the defibrillator is turned off fall within the scope of the applicable claims. The contested issue is, however, whether "prior to any attempted use" includes self tests that are performed after the defibrillator is turned on but before attempted use to treat a patient. Philips asserts that the self test must be performed before the defibrillator is turned on. Zoll proposes a construction in which the self test can occur at any point after the defibrillator is turned on but before it is used to treat a patient. This Court agrees with the Defibtech Court that

> It makes little difference what the phrase 'prior to any attempted use' means, because the claims in which it appears impose modifications that resolve the parties' disputes.

397 2d. at 1268. As a result, the Court will examine the precise use of the term in each of the Claims in which the term appears.

Claim 41 teaches a "periodic test signal generator." Claim 42 states that the test signal will be generated "periodically." According to the "detailed description of the preferred embodiment" in the '374 Patent these periodic self-tests occur daily, weekly or monthly, even when the defibrillator is turned off. Thus, "by their nature, these tests occur before any use of the defibrillator, including merely turning the device on." Id. 1269. As a result, the Defibtech court construed the term when used in Claims 41 and 42 to mean "prior to any attempted use of the defibrillator, even non-therapeutic uses." Although this Court is persuaded by the same reasoning adopted in Defibtech, it prefers the more easily understood construction "prior to an operator turning on the defibrillator."

In Claim 67 the language requires that the generation of a test signal occur "without human intervention." As a result, that language must also refer to one of the periodic self-tests and the status indication must occur prior to turning on the defibrillator. Thus, the Court adopts the same construction as in Claims 41 and 42 where "prior to any attempted use" means "prior to an operator turning on the defibrillator."

Claims 1 and 67 require a different construction. Claim 1 does not indicate which of the multiple types of self-test in the

'374 Patent is required. Claim 1 does not require all of the tests, instead, it requires only one. As the Defibtech Court described, a defibrillator that was designed to conduct a "run time" test and to monitor the defibrillator "continually" would not reveal its status before it was turned on, even though turning it on is a "use." Id. at 1269. Similarly, a defibrillator that could conduct a manual self-test could not indicate its status prior to such a test, even though this test is itself a "use." Id. Thus, it is clear that Philips' proposed construction "prior to an operator turning on the defibrillator" does not accurately express the meaning of this term.

The Defibtech court found that

> the only "uses" of the defibrillator for which the invention of Claim 1 would *invariably* have means to provide an indication of pre-use status are uses in treating a patient.

In the case of a defibrillator capable of running a randomly selected self-test the device would only be guaranteed to "indicate status before anyone used it to treat a patient, but not necessarily before other uses." Id. It is clear, therefore, that in some instances "prior to any attempted use" means "prior to use to treat a patient." In the case of a defibrillator with means to perform a run-time test, however, the term means "prior to an operator turning on the defibrillator." Therefore, with respect to these Claims, the Court adopts the construction "prior to any attempted

use of the defibrillator to treat a patient, and in some cases prior to an operator turning on the defibrillator."

Claim 44 requires a test signal generated "automatically in response to a predetermined event or condition." This Claim includes at least one kind of self-test but does not include the "periodic" self-tests. This Court agrees with the reasoning in Defibtech that if the test is a "run-time" test the status could not be indicated before the defibrillator was turned on. Id. As a result, the Court applies the same construction as in Claim 1.

**5. Test signal** (Philips' '374, '460 Patents)

The dispute surrounding the construction of "test signal" also relates to the Defibtech court's prior construction of the term. In that case, the court acknowledged that the patent claims are "inconsistent" in the use of the term "test signal." Id. at 1267. As a result, the court construed most instances of "test signal" to mean "a signal associated with testing," but in some instances found that "additional claim language limits the term to a 'signal that initiates testing'." Id. ZOLL requests that the Court adopt the Defibtech Court's construction while Philips argues that "a signal associated with testing" is the better construction because it is one that "a jury can apply uniformly across the board, yet still

be understood within the context of each claim."

The Defibtech court found that the claims in the '460 and '374 patents fell into three classes. Id. First, in claims that "expressly disclose one or more self-tests performed 'in response' to the test signal or other stimuli", "the test signal is a signal that initiates a test, not one that performs it." Id. Second, in claims where the test signal is generated by the system monitor, the test signal is also one that initiates testing. Id. Finally, in the third category where the test signals are neither used to initiate self-testing nor generated by the system monitor, the "test signal" is simply "a signal associated with testing." Id. Thus, although "signal associated with testing" applies in the third category, the other two categories require the additional limitation of "a signal that initiates testing."

While generally "the same claim term used in the same patent 'carries the same construed meaning'" this rule applies only if the court is not "otherwise compelled." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003). Here, this Court agrees with the ruling in Defibtech that the limitations in several of the claims require the court to reach two different constructions of "test signal." As a result, the Court construes this term

to mean the following:

| **Construction** | **Patent** | **Claims** |
|---|---|---|
| "A signal that initiates testing" | '374 | 22, 25-27, 42, 44-45, 51-52, 61-62, 64-65, 67-69, 71-72 |
| "A signal that initiates testing" | '460 | 1-6 |
| "A signal associated with testing" | '374 | 1-6, 10, 21, 34-37, 41, 43 |

**6. A heart rate alarm circuit in which the inputs comprise an averaged QRS rate and the shock advisory indication** (ZOLL's '187 Patent)

The Summary of the Invention in ZOLL's '187 Patent states that it features "an alarm driven by both a heart rate detector and a fibrillation/tachycardia advisory algorithm." This distinction sets the '187 patent apart from prior art in which alarms were based on only one of those inputs. Philips requests that the word "both" be added to the claim construction to make this distinction clear. The Court finds, however, that the claim language is already clear that both inputs are required and is capable of being understood correctly by the jury. As a result, the Court declines to construe this term.

**7. Generate an alarm when the monitoring circuitry determines that the external power connection is not connected to a source of external power and that the medical device to which the power supply may be connected is not turned on/Generating an alarm when the external power connection is not connected to the external power source and the medical device is not**

**turned on** (ZOLL's '807 Patent)

Philips argues that the alarm circuitry is configured to generate an alarm "as a result of" the monitoring circuitry determining that the device is both not connected to external power and not turned on. Philips asserts, therefore, that unless the Court construes "when" to mean "as a result of" the causal connection will not be clear to the jury.

The Court finds that the patent does not, however, require that the alarm actually be triggered by the two events but only that the alarm function when the two events occur. Thus, if the power supply is connected to AC power and the defibrillator is turned on the power supply will be prevented from activating the alarm. Because the patent language already makes this relationship clear the Court declines to construe it further.

**8. A method of supplying power from an external power source to a battery-powered medical device for charging a battery of the medical device and operating the medical device** (ZOLL's '807 Patent)

Philips requests that the Court construe the claim language to add the words "by a power supply" to make "the method of supplying power" clear to the jury. This Court, however, agrees with ZOLL that the inclusion is unnecessary. The language in Claim 15 already indicates that "the method of supplying power" includes "providing a power supply." As a result, the additional inclusion is superfluous and the Court declines to construe this term.

**9. Power supply** (ZOLL's '807 Patent)

ZOLL argues that "power supply" is a common term that requires no construction. This Court agrees with Philips, however, that the term requires construction to improve juror comprehension but declines to adopt Philips' proposed construction, particularly the inclusion of the words "connects to a source of AC power." That language is too narrow to address the actual invention. For example, Claim 1 recites a "connection for bringing external power into the power supply." Such language suggests that the power supply does not always connect directly to a source of AC power. Instead, the Court relies on the patent specification to adopt the construction "a unit that connects to a device and that supplies power to the device."

**10. Envelope comprising a sheet of material** (ZOLL's '250 Patent)

The underlying dispute over the two claim terms in the '250 patent relates to whether the "envelope" must be fully enclosed. ZOLL asserts that the term should be given its "ordinary meaning" and thus does not require construction. Philips, on the other hand, relies on the purpose of the invention to argue that an envelope must be an "enclosure." This Court agrees with Philips and construes the term to mean "a sheet of material that forms an enclosure."

Claim 1 teaches that the envelope has a releasable "seal" that forms a "sealed first compartment" and allows the electrodes

to be "isolated from an external environment." This isolation is described as necessary to "prevent[] the adhesive gel from drying out." The Court is persuaded that if the envelope did not "enclose" the electrodes, the gel would dry out and the invention would not work as described. As a result, the Court finds that the "envelope" is an enclosure.

**11. Seal** (ZOLL's '250 Patent)

This term is closely related to the "envelope" construed in the proceeding section. ZOLL argues that the seal need only provide a "barrier" that serves as "something that closes the envelope by joining parts of it together." This construction, however, ignores the purpose of the invention. As Philips points out, a porous barrier could still join the parts together but would not serve the purpose of the invention. If the seal is not airtight, it will not "isolate the electrode from the external environment" as the patent requires.

Further, the '250 patent uses the terms "seal" and "barrier" differently. For example, in Claim 13 the "gasket" that allows the wires that connect to the electrode to pass through the envelope is described as a "barrier element". Because the gasket allows items to pass through, it is not airtight. That word choice suggests that the patentee chose the term "seal" to distinguish from other non-airtight barriers within the same invention. The seal is also repeatedly described as a "heat

seal", which is further evidence that it is intended to be airtight. As a result, the Court construes "seal" to mean an "airtight barrier."

> **12. A concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1Ω when a 200 Joule defibrillation pulse is discharged into the series circuit** (ZOLL's '526 Patent)

ZOLL asserts that no construction is needed. Philips, responds however, that Claim 1 of the '526 patent is indefinite because there is no explanation "for how one skilled in the art would choose specific testing conditions to determine whether the resistance of a given gel electrode is 'greater than 1Ω'." A term is indefinite where the product "might or might not infringe depending on its usage in changing circumstances." Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

According to Philips, gel electrodes are tested under the industry standards for defibrillators set by the Association for Advancement of Medical Instrumentation (AAMI). These standards include a variety of test conditions including the temperature of the gel, the amount of time the gel has been exposed to air (humidity) and the number of shocks delivered through the gel. The '526 patent does not, however, specify the test conditions

necessary to determine whether the claim limitation is met. Philips conducted testing under a variety of temperature conditions. At 35° centigrade ("C") the resistance did not exceed 1Ω but at 15C it did. Thus, depending on the temperature, the same gel electrode may or may not infringe Claim 1. Philips also conducted tests with varying degrees of dryness in the electrode gel and number of shocks to the electrode and elicited results that both did and did not infringe Claim 1.

ZOLL contends that the testing conditions are apparent to a skilled artisan who would know that when testing conditions are not specified the tests should be conducted at room temperature, shortly after removing the electrodes from their packaging and without performing numerous previous shocks. Furthermore, ZOLL argues that Philips fails to mention that the AAMI standards do not include any requisite parameters and thus describe as much as the '526 patent does. Finally, ZOLL asserts that descriptions of electrode resistance tests that do not include those parameters are commonly described in the technical literature.

Patent claims must state with particularity the subject matter which the applicant regards as his invention. 35 U.S.C. § 112. That definiteness requirement serves a public notice function and ensures that patent claims will be "sufficiently precise to permit a potential competitor to determine whether or not he is infringing." Amgen Inc. v. Hoechst Marion Roussel,

Inc., 314 F.3d 1313, 1342 (Fed Cir. 2003) (internal quotation omitted).

Proof of indefiniteness of patent claims, enough to render a patent invalid, is met where an accused infringer shows, by clear and convincing evidence, that a skilled artisan could not discern the bounds of the claim "based upon the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). The bar is high: "a claim is not indefinite merely because its scope is not ascertainable from the face of the claims." Amgen, 314 F.3d at 1342. Instead, it must be "insolubly ambiguous" such that "reasonable efforts at claim construction prove futile." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2010). Indeed,

> Even if it is a formidable task to understand a claim, and the result not unanimously accepted, as long as the boundaries of a claim may be understood it is sufficiently clear to avoid invalidity for indefiniteness.

Invitogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1383 (Fed. Cir. 2005) (internal quotation omitted); see also Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1379 (Fed. Cir. 2001) ("Provided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of the claims does not

render the claims indefinite.").

Although it is true that "the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction," Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (citation omitted), there are several reasons to defer rulings on indefiniteness until the summary judgment stage, CSB-Syst. Int'l Inc. v. SAP Am., Inc., No. 10-2156, 2011 WL 3240838, at *17-18 (E.D. Pa. July 28, 2011). Those reasons include the fact that an allegedly infringing party must prove indefiniteness by "clear and convincing proof" to overcome the statutory presumption of validity and that

> unlike a Markman proceeding that gives meaning to patent claims, indefiniteness invalidates the claims entirely. As such, this dispositive effect is more appropriately tackled at summary judgment.

Id. at *18 (citing numerous instances in which courts elected to defer indefiniteness until summary judgment).

This is not a case where a defense of indefiniteness is based upon claims which, on their face, are so vague that they cannot reasonably be interpreted but rather is a case where the relevant claims can be construed but are alleged to be indefinite as applied. Compare Am. Med. Systs., Inc. v. Biolitec, Inc., 666 F. Supp. 2d. 216, 223 (D. Mass. 2009)(construing a claim as indefinite where claim language was subject to "multiple conflicting interpretations"); with Takeda Pharm. Co. v. Handa

Pharms., LLC, 2012 WL 1243109, at *16 (N.D. Cal. Apr. 11, 2012) (deferring indefiniteness until summary judgment because whether a skilled artisan could determine relevant amounts without undue experimentation was a "largely factual" inquiry). Here, the parties' respective experts offer extrinsic evidence as to whether the disclosure of the patent is sufficient to allow a person of ordinary skill to identify the relevant testing conditions necessary to determine whether the electrode infringes. This "battle of the experts" is not, therefore, properly decided at the claim construction phase.

The Court declines to construe this term. Philips is not, however, foreclosed from challenging the validity of this claim for indefiniteness at summary judgment.

**13. User-triggered inquiry/user-triggered indicator** (Philips' '093 Patent)

The parties agree on the plain and ordinary meaning of "user-triggered." ZOLL, however, requests that the Court add "regardless of whether the defibrillation capability is active or not" to its construction. To support this additional limitation, ZOLL points to the patent specification which contrasts the invention with prior art defibrillators because "the present invention" permits "the user-initiated inquiry to be carried out whether or not the defibrillator is turned on." Philips responds that defibrillation capability is not dependent upon whether the defibrillator is turned on. The Court agrees with Philips and

construes this term according to its ordinary meaning.

**14. Detailed [audio] instructions** (Philips' '785 Patent)

The dispute over this term relates to the level of "detail" the instructions require. The parties agree that the construction of this term should be informed by the prosecution history. The original application recited "prompts" and "instructions" but not "detailed instructions" and was thus rejected because such terms were broad enough to encompass the "sound or flashing light pacing signals" in the prior Lurie patent. In response, the applicants amended their application to include "detailed instructions."

Philips requests that the Court adopt the construction

> [audio] instructions that prescribe a sequence of steps for reviving a patient, such as (1) deliver a number of chest compressions, (2) deliver a certain number of breaths, (3) deliver a certain number of therapeutic shocks, (4) call 911, and/or (5) clear the patient's airway.

To reach that proposed construction, Philips relies on a statement made by the applicants in response to the original patent application rejection that:

> Various forms of detailed instructions are provided in the referenced sections of the written description, including, for example, prompting the caregiver to: deliver a number of chest compressions, deliver a certain number of breaths, deliver a certain number of therapeutic shocks, call 911, and/or clear the patient's airway. This level of instruction is not disclosed in Lurie.

ZOLL responds that the inclusion of the words "such as" in Philips' proposed construction "improperly requires the fact-finder to decide subjectively how detailed an instruction must be." This Court agrees and rejects that construction.

ZOLL, instead, requests that the Court adopt the construction

> [audio] instructions that prescribe a sequence of CPR steps, including the number of times a particular step is to be taken (if the step is to be repeated).

That construction is based on the series of diagrams in Figures 3-17 that the applicants submitted as part of the amended patent application. ZOLL argues that each of those figures "shows a process by which a user is prompted to administer a CPR step a particular number of times." This Court, however, agrees with Philips' contention that the figures are meant only to be illustrative and were not intended to represent all of the invention's functions. Thus, the Court declines to find that the "detailed instructions" must include the specific number of times a step should be repeated.

Furthermore, as the patentee's statements in prosecution quoted above indicate, the "detailed instructions" were intended to include "deliver[ing] a certain number of therapeutic shocks." In fact, several of the flow charts in the figures that ZOLL seeks to rely upon even include a step that asks whether a particular number of "consecutive shocks have been delivered."

At oral argument the parties agreed that the defibrillation shock is not a "CPR step." As a result, ZOLL's construction fails to make clear to the jury that the detailed instructions include both CPR and the invention's core function of providing defibrillator shocks. To address that concern, the Court adopts the construction "[audio] instructions that prescribe a sequence of steps for reviving a patient, including CPR and defibrillation shocks."

**15. Synchronized audible [visual] prompts** (Philips' '785 Patent)

Both parties agree that "synchronized" should be construed to mean that the prompts correspond to steps of the "detailed instructions." Philips requests that the Court construe this term as "audible/visual prompts corresponding to the time at which the step should be performed." ZOLL asserts that "the step" should instead be construed as "a particular step" because otherwise Philips' construction is ambiguous as to which step corresponds to which time. ZOLL's argument is unavailing because no portion of the patent specification requires the additional limitation of "a particular step." Instead, the specification states that "the rate of flashing of the visual prompt may correspond to the timing at which the step, such as CPR, is to be performed." (emphasis added). As a result, the Court adopts Philip's proposed construction.

In accordance with the foregoing,

1) "Monitoring/monitoring. . .during" means:

**"measuring . . . one or more times";**

2) "The discharge step/the discharging step" means

**"the step of discharging the energy source";**

3) The Court **declines to construe** the term "plurality of electronic switches";

4) "Prior to any attempted use of the defibrillator" means

**"prior to any attempted use of the defibrillator to treat a patient, and in some cases prior to an operator turning on the defibrillator"** or **" prior to an operator turning on the defibrillator";**

5) "Test signal" means

**"a signal that initiates testing"** in some claims, and in others, **"a signal associated with testing,"**

| **Construction** | **Patent** | **Claims** |
|---|---|---|
| "A signal that initiates testing" | '374 | 22, 25-27, 42, 44-45, 51-52, 61-62, 64-65, 67-69, 71-72 |
| "A signal that initiates testing" | '460 | 1-6 |
| "A signal associated with testing" | '374 | 1-6, 10, 21, 34-37, 41, 43 |

6) The Court **declines to construe** the term "A heart

rate alarm circuit in which the inputs comprise an averaged QRS rate and the shock advisory indication";

7) The Court **declines to construe** the term "Generate an alarm when the monitoring circuitry determines that the external power connection is not connected to a source of external power and that the medical device to which the power supply may be connected is not turned on/Generating an alarm when the external power connection is not connected to the external power source and the medical device is not turned on";

8) The Court **declines to construe** the term "A method of supplying power from an external power source to a battery-powered medical device for charging a battery of the medical device and operating the medical device";

9) "Power supply" means

**"a unit that connects to a device and that supplies power to the device";**

10) "Envelope comprising a sheet of material" means

**"a sheet of material that forms an enclosure";**

11) "Seal" means

**"airtight barrier";**

12) The Court **declines to construe** the term "A concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1Ω when a 200 Joule defibrillation pulse is discharged into the series circuit";

13) "User-triggered inquiry/user-triggered indicator" means

**"an inquiry that the user may trigger"/ "an indicator that the user may trigger";**

14) "Detailed [audio] instructions" means

**"[audio] instructions that prescribe a sequence of steps for reviving a patient, including CPR and defibrillation shocks";**

15) "Synchronized audible [visual] prompts" means

**"audible/visual prompts corresponding to the time at which the step should be performed".**

**So ordered.**

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated November 26, 2012



*** Current through PL 113-286, approved 12/18/14 ***

TITLE 35. PATENTS
PART III. PATENTS AND PROTECTION OF PATENT RIGHTS
CHAPTER 28. INFRINGEMENT OF PATENTS

**Go to the United States Code Service Archive Directory**

*35 USCS § 271*

THE CASE NOTES SEGMENT OF THIS DOCUMENT HAS BEEN SPLIT INTO 2 DOCUMENTS.
THIS IS PART 1.
USE THE BROWSE FEATURE TO REVIEW THE OTHER PART(S).

§ 271. Infringement of patent

(a) Except as otherwise provided in this *title [35 USCS §§ 1* et seq.], whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 355(j)*] or described in section 505(b)(2) of such Act [*21 USCS § 355(b)(2)*] for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act [*21 USCS § 360b*] or under the Act of March 4, 1913 *(21 U.S.C. 151*-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C) (i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act [*42 USCS § 262(l)(3)*] (including as provided under section 351(l)(7) of such Act [*42 USCS § 262(l)(7)*]), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act [*42 USCS § 262(l)(2)(A)*], an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act [*42 USCS § 262(l)(3)(A)(i)*],

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act [*42 USCS § 262(k)(6)*], in an action for infringement of the patent under section 351(l)(6) of such Act [*42 USCS § 262(l)(6)*], and the biological product has not yet been approved because of section 351(k)(7) of such Act [*42 USCS § 262(k)(7)*].

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285 [*35 USCS § 285*].

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 355*), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent

brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6) (A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent--

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act [*42 USCS § 262(l)(4)*] or the lists of patents described in section 351(l)(5)(B) of such Act [*42 USCS § 262(l)(5)(B)*] with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act [*42 USCS § 262(l)(6)*]; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act [*42 USCS § 262(l)(3)(A)*], including as provided under section 351(l)(7) of such Act [*42 USCS § 262(l)(7)*] for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.